

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**FEDERAL TRADE COMMISSION,
STATE OF ILLINOIS, and
STATE OF MINNESOTA,**

Plaintiffs,

v.

**GTCR, LLC,
GTCR BC HOLDINGS, LLC, and
SURMODICS, INC.,**

Defendants.

Case No. 1:25-cv-02391

District Judge Jeffrey I. Cummings

DEFENDANTS' PROPOSED FINDINGS OF FACT & CONCLUSIONS OF LAW

TABLE OF CONTENTS

	<u>PAGE</u>
DEFENDANTS’ PROPOSED FINDINGS OF FACT.....	1
I. INTRODUCTION	1
II. THE LUBRICIOUS COATINGS INDUSTRY	4
A. Lubricious Coatings Differ In Their Chemistry, Application, And Capabilities	5
B. Customers Have Many Lubricious Coating Suppliers To Choose From	8
C. OEMs May Also Choose To Manufacture Their Own “In-House” Coatings	9
D. Medical Device Manufacturers Select Coatings Based On Performance And Their Manufacturing Processes And Equipment	11
E. Competition To Coat A Medical Device Is Device Specific	15
F. Once A Medical Device Receives FDA Approval, Switching Coating Suppliers Is Commercially Infeasible	18
G. Commercialized Medical Devices Are Governed By Long-Term Agreements	20
H. The Vast Majority Of The Parties’ Current Revenues Come From Contracts Won Years Ago From Coatings That Are No Longer Marketed.....	21
III. THE PROPOSED ACQUISITION OF SURMODICS AND DIVESTITURE TO INTEGER WILL BENEFIT CUSTOMERS AND ENHANCE COMPETITION	23
A. BC Holdings Is Acquiring Surmodics To Build A Broader Platform For Customers And Become A “One-Stop Shop” For Medical Device Customers	24
B. The Divestiture To Integer Creates A New Hydrophilic Coatings Competitor	26
C. Integer Is Uniquely Situated To Compete Immediately And Has Everything It Needs To Do So.....	29
1. Integer Is A Strong, Well-Positioned Buyer With Over 20 Years Experience With Hydrophilic And Other Coatings	29

2.	Integer Is Committed To A Strategy To Offer Coatings As A Service Offering, With the Goal To Be A “One-Stop Shop” For Its Customers	31
3.	Integer Offers Benefits To Customers That The Merged Biocoat-Surmodics Entity Will Not.....	33
4.	Integer Is Experienced In Acquisitions and Integrating Operations	35
5.	Integer Will Be Able To Compete On Day One.....	37
6.	The Divestiture Purchase Price Reflects An Arm’s Length Negotiation.....	41
7.	Integer Will Be A Formidable Innovator And Competitor Going Forward.....	42
IV.	PLAINTIFFS FAIL TO DEMONSTRATE THAT “OUTSOURCED HYDROPHILIC COATINGS” IS A RELEVANT PRODUCT MARKET	44
A.	Plaintiffs’ Alleged Relevant Market Is Inconsistent With “Commercial Realities” And Lacks Factual And Economic Support.....	44
B.	The <i>Brown Shoe</i> Factors Do Not Support Plaintiffs’ Market Definition.....	46
C.	Dr. Fix’s Relevant Market “Analysis” Is Unavailing Because It Fails To Account For Heterogeneity In Demand Or Differentiation In Supply	48
D.	Dr. Fix’s Hypothetical Monopolist Test Cannot Save Plaintiffs’ Market Definition	51
V.	PLAINTIFFS FAIL TO SHOW UNDUE CONCENTRATION IN ANY RELEVANT MARKET.....	53
A.	Dr. Fix’s Revenue-Based Market Shares Are Unreliable And Biased	53
B.	Dr. Fix’s Alternative Market Shares Based On “New Customer Revenues” Are Flawed As Well.....	56
C.	Dr. Fix’s Alternative Market Shares Based On Feasibility Testing Revenue Also Are Unreliable And Biased	58
D.	None Of Dr. Fix’s Market Shares Reliably Account For The Divestiture	59
E.	Properly Calculated Market Shares Raise No Competitive Concern	59

VI.	THE MODIFIED TRANSACTION IS NOT LIKELY TO LEAD TO A SUBSTANTIAL REDUCTION OF COMPETITION IN ANY RELEVANT MARKET	63
A.	Plaintiffs’ Market Shares Inaccurately Predict The Modified Transaction’s Probable Effect On Competition.....	63
B.	The Divestiture Eliminates Any Possibility Of Anticompetitive Effects	63
C.	Plaintiffs Fail To Demonstrate That There Is Currently Meaningful And Frequent “Head-to-Head” Competition Between Biocoat And Surmodics.....	63
D.	Price Is Rarely A Consideration When Choosing A Coating Supplier	67
E.	Plaintiffs Did Not Put Forward Any Evidence Of Actual Consumer Harm From The Original Or Modified Transaction	68
F.	Dr. Fix’s “Merger Simulation” Is Irrelevant Because It Does Not Align With Competitive Realities Or Account For The Divestiture	70
VII.	CREDIBILITY FINDINGS.....	71
VIII.	THE EQUITIES WEIGH AGAINST AN INJUNCTION	73
	CONCLUSIONS OF LAW	75
IX.	LEGAL STANDARDS	75
A.	The Preliminary Injunction Standard: Section 13(b) Of The FTC Act	75
B.	The Substantive Law: Section 7 Of The Clayton Act And The <i>Baker-Hughes</i> Burden Shifting Framework	77
C.	The Relevant Transaction Includes The Divestiture.....	78
X.	STEP 1: PLAINTIFFS FAIL TO SHOW THAT THEY ARE LIKELY TO SUCCEED IN PROVING THAT THE MODIFIED TRANSACTION WILL RESULT IN UNDUE CONCENTRATION IN ANY RELEVANT MARKET	79
A.	Plaintiffs Are Not Likely To Establish That “Outsourced Hydrophilic Coatings” Is A Relevant Market.....	79
1.	Plaintiffs’ “Outsourced Hydrophilic Coatings” Market Does Not Survive Scrutiny Under The <i>Brown Shoe</i> “Practical Indicia”	82
a.	UV Versus Thermal	83
b.	Hydrophilic Versus Hydrophobic	83

c.	Outsourced Versus In-House	84
2.	Plaintiffs Are Unable To Define A Relevant Market Using Dr. Fix's HMT	84
B.	Plaintiffs Failed To Reliably Demonstrate Undue Concentration In Any Relevant Market.....	86
C.	Plaintiffs Cannot Save Their <i>Prima Facie</i> Case By Arguing That The Merger Eliminates Head-to-Head Competition.....	89
XI.	STEP 2: DEFENDANTS ARE LIKELY TO REBUT PLAINTIFFS' <i>PRIMA FACIE</i> CASE	91
A.	Plaintiffs' Revenue-Based Market Shares Inaccurately Reflect The Modified Transaction's Probable Effects On Competition	92
B.	The Divestiture Eliminates Any Possibility Of Anticompetitive Effects	92
XII.	STEP 3: PLAINTIFFS CANNOT CARRY THEIR ULTIMATE BURDEN OF PERSUASION TO PROVE THE TRANSACTION IS LIKELY TO PRODUCE ANTICOMPETITIVE EFFECTS IN ANY RELEVANT MARKET.....	96
XIII.	THE EQUITIES WEIGH AGAINST AN INJUNCTION	99

TABLE OF AUTHORITIES**Page(s)****CASES**

<i>Astellas US Holding, Inc. v. Fed. Ins. Co.</i> , 66 F.4th 1055 (7th Cir. 2023)	79
<i>Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.</i> , 784 F.2d 1325 (7th Cir. 1986)	86
<i>Brown Shoe Co. v. United States</i> , 370 U.S. 294 (1962)	76, 79, 82
<i>FTC v. Arch Coal, Inc.</i> , 2004 WL 7389952 (D.D.C. July 7, 2004)	78
<i>FTC v. Arch Coal, Inc.</i> , 329 F. Supp. 2d 109 (D.D.C. 2004)	<i>passim</i>
<i>FTC v. Cardinal Health, Inc.</i> , 12 F. Supp. 2d 34 (D.D.C. 1998)	84
<i>FTC v. CCC Holdings Inc.</i> , 605 F. Supp. 2d 26 (D.D.C. 2009)	85
<i>FTC v. Elders Grain, Inc.</i> , 868 F.2d 901 (7th Cir. 1989)	77, 100
<i>FTC v. Great Lakes Chem. Corp.</i> , 528 F. Supp. 84 (N.D. Ill. 1981)	82, 99, 100
<i>FTC v. IQVIA Holdings Inc.</i> , 710 F. Supp. 3d 329 (S.D.N.Y. 2024)	81, 90, 98, 99
<i>FTC v. Libbey, Inc.</i> , 211 F. Supp. 2d 34 (D.D.C. 2002)	78
<i>FTC v. Lundbeck, Inc.</i> , 650 F.3d 1236 (8th Cir. 2011)	80, 83
<i>FTC v. Meta Platforms, Inc.</i> , 654 F. Supp. 3d 892 (N.D. Cal. 2023)	76
<i>FTC v. Microsoft Corp.</i> , 681 F. Supp. 3d 1069 (N.D. Cal. 2023)	75, 78

<i>FTC v. OSF Healthcare Sys.</i> , 852 F. Supp. 2d 1069 (N.D. Ill. 2012)	76
<i>FTC v. RAG-Stiftung</i> , 436 F. Supp. 3d 278 (D.D.C. 2020)	<i>passim</i>
<i>FTC v. Staples, Inc.</i> , 190 F. Supp. 3d 100 (D.D.C. 2016)	97
<i>FTC v. Sysco Corp.</i> , 113 F. Supp. 3d 1 (D.D.C. 2015)	80, 91, 95, 98
<i>FTC v. Tapestry</i> , 755 F. Supp. 3d 386 (S.D.N.Y. 2024)	91
<i>FTC v. Tempur Sealy Int’l, Inc.</i> , 768 F. Supp. 3d 787 (S.D. Tex. 2025)	<i>passim</i>
<i>FTC v. Tenet Health Care Corp.</i> , 186 F.3d 1045 (8th Cir. 1999)	76, 77, 79, 89
<i>FTC v. The Kroger Co.</i> , 2024 WL 5053016 (D. Or. Dec. 10, 2024)	90, 95, 96, 98
<i>FTC v. Thomas Jefferson Univ.</i> , 505 F. Supp. 3d 522 (E.D. Pa. 2020)	89, 100
<i>FTC v. Weyerhaeuser Co.</i> , 665 F.2d 1072 (D.C. Cir. 1981)	99
<i>FTC v. Whole Foods Mkt., Inc.</i> , 548 F.3d 1028 (D.C. Cir. 2008)	90, 98, 99
<i>FTC v. Wilh. Wilhelmsen Holding ASA</i> , 341 F. Supp. 3d 27 (D.D.C. 2018)	98, 99
<i>Gavin v. AT&T Corp.</i> , 2004 WL 2260632 (N.D. Ill. Sept. 30, 2004)	23
<i>GTCR BC Holdings, LLC</i> , No. 9440 (F.T.C. June 10, 2025)	73
<i>Illumina, Inc. v. FTC</i> , 88 F.4th 1036 (5th Cir. 2023)	96
<i>In re Harley-Davidson Aftermarket Parts Mktg., Sales Pracs. & Antitrust Litig.</i> , ___ F.4th ___, 2025 WL 2374859 (7th Cir. Aug. 15, 2025)	82

<i>In the Matter of Tempur Sealy Int’l, Inc.</i> , 2024 WL 4544179 (F.T.C. Oct. 15, 2024).....	75
<i>Int’l Shoe Co. v. FTC</i> , 280 U.S. 291 (1930).....	77, 96
<i>Kaiser Aluminum & Chem. Corp. v. FTC</i> , 652 F.2d 1324 (7th Cir. 1981)	<i>passim</i>
<i>Ky. Speedway v. NASCAR, Inc.</i> , 588 F.3d 908 (6th Cir. 2009)	82
<i>LSP Transmission Holdings II LLC v. Huston</i> , 131 F.4th 566 (7th Cir. 2025)	75
<i>New York v. Deutsche Telekom AG</i> , 439 F. Supp. 3d 179 (S.D.N.Y. 2020).....	97
<i>Ohio v. Am. Express Co.</i> , 585 U.S. 529 (2018).....	79
<i>Ortho Diagnostic Systems v. Abbott Laby’s</i> , 920 F. Supp. 455 (S.D.N.Y. 1996).....	87
<i>ProMedica Health Sys., Inc. v. FTC</i> , 749 F.3d 559 (6th Cir. 2014)	90
<i>Reifert v. S. Cent. Wis. MLS Corp.</i> , 450 F.3d 312 (7th Cir. 2006)	85
<i>Spectrofuze Corp. v. Beckman Instruments, Inc.</i> , 575 F.2d 256 (5th Cir. 1978)	84
<i>Starbucks Corp. v. McKinney</i> , 144 S. Ct. 1570 (2024).....	75, 76
<i>Times-Picayune Pub. Co. v. United States</i> , 345 U.S. 594 (1953).....	80
<i>United States v. Aetna</i> , 240 F. Supp. 3d 1 (D.D.C. 2017).....	95, 97
<i>United States v. Anthem, Inc.</i> , 236 F. Supp. 3d 171 (D.D.C. 2017).....	97
<i>United States v. Baker Hughes Inc.</i> , 908 F.2d 981 (D.C. Cir. 1990).....	77, 79, 91, 96

<i>United States v. Bayer AG</i> , 2019 WL 1431903 (D.D.C. Feb. 8, 2019)	94
<i>United States v. Citizens & S. Nat’l Bank</i> , 422 U.S. 86 (1975).....	76
<i>United States v. Continental Can</i> , 378 U.S. 441 (1964).....	80
<i>United States v. E.I. du Pont de Nemours & Co.</i> , 353 U.S. 586 (1957).....	89
<i>United States v. Engelhard Corp.</i> , 126 F.3d 1302 (11th Cir. 1997)	80
<i>United States v. Gen. Dynamics Corp.</i> , 415 U.S. 486 (1974).....	86, 87, 88
<i>United States v. H & R Block, Inc.</i> , 833 F. Supp. 2d 36 (D.D.C. 2011).....	80, 98, 99
<i>United States v. Int’l Harvester Co.</i> , 564 F.2d 769 (7th Cir. 1977)	86
<i>United States v. Int’l Tel. & Tel. Corp.</i> , 1971 WL 541 (N.D. Ill. July 2, 1971).....	84
<i>United States v. Marine Bancorporation, Inc.</i> , 418 U.S. 602 (1974).....	79
<i>United States v. Oracle Corp.</i> , 331 F. Supp. 2d 1098 (N.D. Cal. 2004)	89, 98
<i>United States v. Phila. Nat. Bank</i> , 374 U.S. 321 (1963).....	89
<i>United States v. Sabre Corp.</i> , 452 F. Supp. 3d 97 (D. Del. 2020).....	85
<i>United States v. Sungard Data Sys., Inc.</i> , 172 F. Supp. 2d 172 (D.D.C. 2001).....	<i>passim</i>
<i>United States v. U.S. Sugar Corp.</i> , 73 F.4th 197 (3d Cir. 2023)	81, 82, 85, 86
<i>United States v. UnitedHealth Grp. Inc.</i> , 630 F. Supp. 3d 118 (D.D.C. 2022).....	<i>passim</i>

<i>United States v. Waste Mgmt., Inc.</i> , 743 F.2d 976 (2d Cir. 1984).....	86, 87, 88
<i>White Consol. Indus., Inc. v. Whirlpool Corp.</i> , 781 F.2d 1224 (6th Cir. 1986)	100

STATUTES

15 U.S.C.	
§ 18.....	<i>passim</i>
§ 18a.....	23
§ 18a(a)	75
§ 53(b).....	75, 76, 99, 100

RULES

Fed. R. Evid. 301	77
-------------------------	----

REGULATIONS

16 C.F.R.	
§ 801.1(a)(1)	23, 75
§ 801.1(a)(3)	23

OTHER AUTHORITIES

DOJ & FTC Merger Guidelines § 4.4.B (2023)	87
FTC, Bureau of Competition, Statement on Negotiating Merger Remedies (Jan. 2012), https://www.ftc.gov/system/files//negotiating-merger-remedies/merger-remediesstmt.pdf	93, 94

TABLE OF ABBREVIATIONS

Abbreviation	Source
¶	Paragraph in Defendants' Proposed Findings of Fact and Conclusions of Law
Tr.	Preliminary Injunction Hearing Transcript
Dep.	Deposition Transcript
Rep.	Expert Report
Ankeny	Phillip Ankeny, Chief Financial Officer, Harland Medical Systems
Borgaonkar	Harshad Borgaonkar, Senior Director of Research & Development, Heraeus Medevio
Brenizer	Joshua Brenizer, Senior Principal, Research & Development Engineer, Teleflex
Dang	Kenny Dang, Chief of Staff, Terumo Neuro
de Freitas	Joshua de Freitas, Head of Business Development and Sales, Biocoat
Eccles	William Eccles, Vice President of Research and Development, Scientia Vascular
Epps	Jeannie Epps, Director of Applied Technology and Evaluation, Terumo Medical Corp.
Fix	Dr. Aaron Fix, Staff Economist, Bureau of Economics - Federal Trade Commission (Plaintiffs' Expert)
Gronda	Ann Gronda, Senior Principal Chemical Engineer and Technical Fellow, Medtronic
Hance	Robert Hance, CEO and Chairman, Biocoat
Hatcher	Brady Hatcher, CEO, Switchback Medical
Hergenrother	Dr. Robert Hergenrother, Vice President of Research, Development, and Innovation, Biocoat
Hiatt	Mark Hiatt, Director of Post-Market Engineering, Cook Medical
Hutar	Jared Hutar, CEO, Piraeus Medical
Jalgaonkar	Ujwal Jalgaonkar, Vice President of Research & Development, Balt USA
Johnson	Bart Johnson, Senior Director of Ophthalmic Instrumentation Platforms in R&D, Johnson & Johnson Surgical Vision
Juntunen	Andrew Juntunen, Senior Category Manager, Adhesives and Specialty Coatings, Medtronic
Lydon	Margaret Lydon, Director of Plant Operations, Argon Medical Devices

Abbreviation	Source
Maharaj	Gary Maharaj, President and CEO, Surmodics
Marker	Luke Marker, Managing Director, GTCR LLC, and Biocoat Board Member
Martin	Brian Martin, President and Chief Technology Officer, Maduro Medical
McCormack	Patrick McCormack, Senior Director, Research & Development, Stryker
Moll	Andrew Moll, Research & Development Director, Becton Dickinson
Moran	James Moran, Senior Adviser (former CEO), Biocoat
Nair	Rahul Nair, former GTCR associate
Owens	Michael Owens, Vice President of R&D, Philips Healthcare
Patrick	Bryan Patrick, CEO, Midwest Interventional Systems
D. Patel	Dhruv Patel, Principal Technical Sales Engineer, Integer
H. Patel	Himanshu Patel, former Chief Technology Officer, Avinger
Petra	Danielle Petra, Global Business Director for Polyethylene Solutions and Coating Solutions, DSM Biomedical
Rentschler	Mark Rentschler, CEO, Aspero Medical
Senn	Andrew Senn, President Cardio & Vascular Division, Integer
Shrivastava	Sanjay Shrivastava, CEO, Innova Vascular
Stephens	William Stephens, Vice President of Global Research, Technology and Development, Shockwave Medical
Stern	David Stern, President and COO, Contego Medical
Tieso	Tristan Tieso, COO, Fastwave Medical
Tompkins	Ben Tompkins, Executive Vice President of Development and Compliance, Penumbra
Torti	Michael Torti, CEO, Hydromer
Ventura	Joe Ventura, Senior Director of Business Development, Surmodics
Welsh	Greg Welsh, COO, Alembic
Wong	Dr. Paul Wong, Managing Director, NERA (Defendants' Expert)

DEFENDANTS' PROPOSED FINDINGS OF FACT

I. INTRODUCTION

1. As the preliminary injunction hearing made clear, there is no evidence that GTCR BC Holdings, LLC's ("BC Holdings") acquisition of Surmodics, Inc. ("Surmodics") (the "Original Transaction"), let alone the transaction before the Court that includes the divestiture of certain of Biocoat's assets to Integer Holdings Corp. ("Integer") (the "Modified Transaction" or "Divestiture"), is likely to substantially lessen competition in Plaintiffs' purported "outsourced hydrophilic coatings" market. Plaintiffs failed to show that medical device customers will face higher prices for hydrophilic coatings or suffer from lower quality services or less innovative products.

2. Instead, the evidence shows that the Modified Transaction will create a new hydrophilic coating supplier in Integer that is uniquely positioned to compete vigorously, which it intends to do from Day One. Integer's Cardio & Vascular President Andrew Senn, whose team is responsible for integrating the divested Biocoat assets, testified that Integer is receiving everything it needs to successfully manufacture, innovate, and sell UV and thermal hydrophilic coatings, and that it will be positioned to effectively compete, and intends to compete, with the merged firm immediately. Section III.C. Even Plaintiffs' expert, Dr. Aaron Fix, agrees there is no "reason to doubt" Mr. Senn's intentions. Tr. 1190:25-1191:6, 1197:5-13 (Fix). The Divestiture to Integer thus resolves any possible concerns regarding the competitive effects of BC Holdings's acquisition of Surmodics.

3. To obtain a preliminary injunction, Plaintiffs must make a "clear showing" of a likelihood of success on the merits, which requires demonstrating—based on record evidence and not just speculation or mere possibility—that there is a "reasonable probability or appreciable danger" that the Modified Transaction "may substantially lessen competition." Section IX. Plaintiffs have not met their burden. Sections IV-VI, X.

4. Plaintiffs have not demonstrated a *prima facie* case under Step 1 of the *Baker Hughes* framework. First, they fail to show that “outsourced hydrophilic coatings” is a properly defined relevant market, because (i) not all interventional medical devices can use both thermal and UV-cured coatings (Section II.A); (ii) many of the same types of medical devices (*e.g.*, guidewires and catheters) also use other types of coatings, or no coating (*id.*); and (iii) many OEMs use their own in-house coatings as alternatives to outsourcing (Section II.C). Plaintiffs ignore evidence, provided by virtually every witness including their own economic expert, that coating selection is customer and medical device specific, depending on the physics, chemistry, and geometry of the device’s substrate and its intended clinical use, the customer’s investment in equipment and its manufacturing processes, and other factors. Sections II.D-E. UV coatings will not work on device geometries where light cannot penetrate, including the inner diameters of catheters, and thermal coatings will not work on heat sensitive substrates that may melt when exposed to heat or cause the coating to crack when they expand, including balloons. Section II.D. Even where either a UV or thermal coating could work, other types of lubricious coatings or materials (including hydrophobic coatings) or no surface modifications at all, may be substitutes. Section II.A. Plaintiffs’ purported relevant market is thus too narrow and too broad, fails to fit the heterogenous needs of customers, fails to reflect commercial realities in the lubricious coatings industry, and is unsupported by any reliable economic analysis.

5. Second, even within Plaintiffs’ flawed “outsourced hydrophilic coatings” market, Plaintiffs have not demonstrated that the Modified Transaction (or the Original Transaction) is likely to result in undue concentration. Section V. Plaintiffs’ market share calculations, which are based on the parties’ revenues, do not accurately or reliably measure current or future competitive significance, but rather largely reflect coatings competition won many years ago and the ultimate commercial

success (or failure) of the coated medical device. Section V.A. Relying on publicly available FDA data, which reflects competition that is actually occurring today, Defendants' expert, Dr. Paul Wong, found that the parties have "very modest" market shares that are below the 30% threshold for triggering any competitive concern, even under conservative assumptions. Section V.E.

6. Neither the evidence nor the law supports Plaintiffs' alternative theory that they can establish their *prima facie* case by showing Biocoat and Surmodics engage in "fierce head-to-head competition" at "every stage." Tr. 1954:25-1955:3, 1955:9-13 (Pls. Closing); Section X.C. There is no evidence that any of the supposed instances of "head-to-head" competition resulted in meaningful price or quality outcomes for customers for any commercialized device. Section VI.C. Rather, in virtually all instances where a customer considered both Biocoat and Surmodics to coat a medical device, other coating suppliers were also considered, or either Biocoat's or Surmodics's coating failed to work on the device, rendering it not a viable option for that device. *Id.* The evidence also shows that medical device customers select coatings primarily based on performance and do not play coating suppliers off each other to obtain better pricing. Section VI.D.

7. Moreover, the evidence demonstrates that once a coating is selected for a device and the FDA approves that device (with that coating), it is commercially infeasible to change coatings. Section II.F. Once a coating is selected, and the device receives FDA approval, the coating is "locked in" for the device's lifetime, which can be decades. *Id.* There is not a single example in the record of a medical device customer changing coatings on a commercialized device after receiving FDA approval. *Id.* This further confirms that Plaintiffs' market share figures based on the parties' revenues, which reflect competition for devices won many years ago, are an unreliable predictor of present or future competition or the parties' competitive significance. Sections V.A, VI.A. There is thus no need for the Court to even reach Step 2 of the *Baker Hughes* analysis.

8. If the Court were to advance to Step 2, Defendants produced ample evidence demonstrating that Plaintiffs’ *prima facie* case inaccurately predicts the Modified Transaction’s probable effect on future competition. *Id.*; Section XI.

9. In addition to the lack of evidence of “head-to-head competition” that results in meaningfully different outcomes for customers, there also is no evidence that any harm to medical device customers is likely to result from the Modified Transaction (or Original Transaction). There is no evidence that the merged firm intends to (or could) raise prices if the transaction is consummated. Section VI.E. Nor is there any evidence that there will be less innovation as a result of the Modified Transaction—indeed, the record demonstrates the opposite is likely to be true, as the Divestiture will create in Integer a net new thermal supplier. Section VI.B. For that reason, numerous customers, including Plaintiffs’ own witnesses, testified that they are not concerned about the Original Transaction or the Modified Transaction, a rare fact pattern for a merger litigation. Section VI.E.

10. The evidentiary record from the hearing confirms that Plaintiffs’ theory of anticompetitive effects is based on speculation and conjecture, including their unsupported concern that Integer might not be as successful as Integer intends and expects. Section III.C. But theory and speculation cannot trump facts, and this speculation fails to satisfy Plaintiffs’ burden of demonstrating that the Modified Transaction is likely to substantially lessen competition in any relevant market. Defendants respectfully request that the Court deny Plaintiffs’ motion for a preliminary injunction, and that it allow the Modified Transaction to proceed.

II. THE LUBRICIOUS COATINGS INDUSTRY

11. Lubricous coatings are applied to interventional medical devices (such as catheters and guidewires) to help physicians navigate tortuous pathways in the body while minimizing trauma to patients. Tr. 468:12-23 (Eccles); 728:6-11 (Gronda).

12. There are many ways to add lubricity to medical devices, including through the use of (1) hydrophilic coatings; (2) hydrophobic coatings, including PTFE, parylene, and silicone oil; (3) lubricious additives; and (4) slippery materials that do not require an additional coating. Tr. 573:24-574:11, 594:13-595:1 (de Freitas); [REDACTED]; [REDACTED]; 1417:20-24, 1419:6-11 (Hergenrother); [REDACTED].

13. While these different technologies all serve the same purpose—providing lubricity to medical devices—the available choices of a lubricious coating or alternative, including surface modifications or no coating, depend on the particular medical device. Tr. 573:24-574:14 (de Freitas); *see also* Section II.E.

A. Lubricious Coatings Differ In Their Chemistry, Application, And Capabilities

14. There are two types of hydrophilic coatings: UV-cured and thermal-cured. Tr. 1420:14-20 (Hergenrother). Curing refers to the process of attaching the coating to the surface of a medical device (*i.e.*, the substrate). *Id.* 1423:7-13. UV coatings are cured with UV light, and thermal coatings are cured in an oven with heat. *Id.* 1420:21-1421:12.

15. UV and thermal coatings differ chemically. Biocoat’s thermal coatings have a topcoat made from hyaluronic acid and a hydrophobic polymer base coat, while its UV coatings have a topcoat made of PVP polymers. Tr. 524:20-22 (de Freitas); 1294:10-21, 1307:8-22 (Hance); 1422:5-1423:2, [REDACTED] (Hergenrother). [REDACTED].

16. Hydrophobic coatings, which repel water, can be made from PTFE (“Teflon”), silicone oil, or parylene. Tr. 973:2-10 (Stern); 1417:20-24 (Hergenrother). Hydrophobic coatings tend to be more durable than hydrophilic coatings. Tr. 229:3-5 (Ankeny) (agreeing that “guidewires are often coated with PTFE because it is very hard and durable”); 1417:25-1418:9 (Hergenrother) (“hydrophobic [coatings] tend to be fairly durable”). [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED].

17. Not all lubricious coatings work on all medical devices, and industry trends predict growth in applications where one of either UV or thermal hydrophilic coatings are unavailable. Tr. 1292:19-1293:14, 1310:8-1311:21 (Hance) (describing industry trends towards UV coatings for catheters “using softer and softer polymers” that are “more sensitive to thermal,” towards thermal coatings on inner diameters “to replace PTFE liners,” and towards thermal coatings on metal needles where “a thermal-cure coating could be very additive”). UV coatings typically do not work on the inner diameter of catheters because the UV light cannot reach the interior of the tube. Tr. 89:23-90:3 (Juntunen) (“you cannot typically use UV coatings on the inner diameter of tubes, because you can’t get the light to penetrate to cure”); [REDACTED]

[REDACTED]; 310:14-16 (Petra) (agreeing that “UV curing cannot be used to coat the inner diameter of a catheter”); 1291:23-1292:16 (Hance) (“[Y]ou can only reach an inner diameter with a coating via heat UV can’t access that.”); [REDACTED]

[REDACTED].

18. Similarly, thermal coatings typically do not work on balloon catheters or soft polymers that are heat-sensitive. Tr. 310:6-12 (Petra) (agreeing that “a substrate that cannot stand high temperatures cannot be used with a thermally-cured coating” because it “would melt”); 1292:2-18 (Hance) (“[S]oft balloon angioplasty catheters ... utilize exclusively ... UV-cured coatings because the soft balloon materials ... can soften or melt in ... an oven.”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]. Thermal coatings also are typically better able to cure to metal substrates.
Tr. 1294:22-1295:6 (Hergenrother).

19. Some medical devices can be coated with a hydrophobic or hydrophilic coating. Tr. 678:6-18 (de Freitas) (agreeing that “hydrophobic coatings are an alternative to both the inner and outer diameters of devices,” and providing an example of a guidewire that selected PTFE instead of a hydrophilic coating); [REDACTED]

[REDACTED]; 987:1-8 (Stern) (“hydrophobic materials” can be used on “metal devices,” and both hydrophilic and hydrophobic coatings can be used on guidewires); [REDACTED]

[REDACTED]
[REDACTED].
20. Some catheters and guidewires can perform their intended clinical uses without any lubricious coating. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]; Owens Dep. (July 15) 90:4-21 (it would be feasible for Philips not to use a

hydrophilic coating for some devices); Jalgaonkar Dep. 73:24-74:14 (Balt has multiple devices that do not require a hydrophilic coating).

B. Customers Have Many Lubricious Coating Suppliers To Choose From

21. Companies that supply UV hydrophilic coatings include: Biocoat, DSM, Harland, Innovative Surface Technologies (“ISurTec”), Noanix, and Surmodics, among others. Tr. 1297:22-1298:4 (Hance) (Surmodics, Harland, ISurTec, DSM, and a “growing Asian cohort of companies” are “options for UV-cured coatings,” in addition to in-house coatings); 339:1-2 (Petra) (DSM offers a UV coating); 592:2-12 (de Freitas) (Noanix and DSM sell in the U.S.); DX-290.002 (“Surmodics, DMS Biomedical [sic], Isurtec and Harland Medical Systems” are UV competitors); DX-736.236 (Wong Rep.); DX-414.001.

22. [REDACTED]

23. Hydrophobic coating suppliers include [REDACTED], Precision Coating, and VSi Parylene. Integer owns Precision Coating and VSi Parylene. [REDACTED]; DX-107.009; [REDACTED].

24. Medical device customers can, and do, consider several suppliers when selecting a lubricious coating. [REDACTED]

25. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

26. Fastwave considered DSM, Harland, Surmodics, Biocoat, and jMedTech when considering UV suppliers for its balloon catheters in development. Tieso Dep. 54:18-57:5, 57:16-19, 122:13-18, 133:9-134:6; PX3042; DX-082.001.

27. Medical device manufacturers also regularly select coating suppliers other than Surmodics or Biocoat. [REDACTED]

[REDACTED]

[REDACTED]; Brenizer Dep. 93:4-18 (Teleflex turns to Harland due to their “long relationship” and “good history”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. OEMs May Also Choose To Manufacture Their Own “In-House” Coatings

28. Some OEMs manufacture their own “in-house” hydrophilic coatings. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

29. Other medical device manufacturers are considering developing in-house coatings as an alternative to outsourcing. [REDACTED]

[REDACTED]

[REDACTED]

30. Defendants' expert, Dr. Wong, identified at least 19 medical device customers that either have in-house coatings or are in the process of developing them, including some of the largest OEMs. Tr. 1576:18-1577:3 (Wong); *see also* DX-736.156-.157, .229-.235 (Wong Rep.). According to Dr. Wong's analysis, the 19 customers with in-house coatings accounted for more than 36% of coating eligible medical devices from 2014-2024. Tr. 1576:21-1577:3 (Wong); DX-736.156 (Wong Rep.)

31. Coating suppliers recognize that customers can turn to in-house coatings. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Biocoat recognizes that it “compete[s] against in-house coatings.” Tr. 669:6-25 (de Freitas). The same is true of Surmodics. Tr. 1024:8-1026:12 (Maharaj) (“the large strategics” “can and often do choose to develop their own performance coatings”) (discussing DX-208.014).

D. Medical Device Manufacturers Select Coatings Based On Performance And Their Manufacturing Processes And Equipment

32. Whether a lubricious coating is an available option for a particular medical device is determined through testing. Customers will not select a coating unless they have tested it to confirm that it satisfies the medical device’s performance requirements and FDA safety standards. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]; Welsh Dep. 42:19-24, 87:22-88:9 (Alembic “would never submit anything to the FDA if it doesn’t pass [the product’s] specification,” and “[y]ou don’t know if you have a good coating unless you test it for that application, for that product substrate”); McCormack Dep. 101:4-7 (agreeing that “you have to test coatings on medical devices before you are able to secure FDA clearance”).

33. Unless and until a coating is tested on a given medical device, neither the coating supplier nor medical device manufacturer know whether the coating will work. Tr. 1291:8-18 (Hance) (“Even though you could think they might work, you don’t really know until you test and see how they perform”); 1425:17-1426:4 (Hergenrother) (“on a particular device, the way it’s made up, and there’s various additives in there, multiple materials, that can affect how well the coating works”); Welsh Dep. 77:15-21 (Alembic thought that Surmodics’s coating would work based on prior experience, but the “Surmodics’[s] UV coating did not ultimately work”). If a coating does

not meet a device's performance requirements, or the FDA's safety requirements, it is not a viable option. Welsh Dep. 41:13-20, 41:22-42:5; [REDACTED]

34. Biocoat Head of Business Development and Sales Josh de Freitas testified that of all opportunities that come to Biocoat's door—which are just “a small fragment of the overall demand in the market” to start—Biocoat sees about 50% decline in opportunities at the feasibility testing stage and a further 50% decline at the optimization stage, due to factors largely outside of Biocoat's control, including changes in the customer's design and materials, the coating did not work, or the project got cancelled. Tr. 580:18-582:2 (de Freitas).

35. If a coating does not work on a device, there is no discount a coating supplier could offer a customer that would persuade the customer to use that coating. Tr. 580:10-17 (de Freitas) (“Q. If you lower prices to the lowest possible price at this stage, could you still win the business? A. If it doesn't work on their devices, there's no business to be won.”); 1415:23-1416:4 (Hergenrother) (“if the coating's not working, in my view, we can't really give it away”); [REDACTED]
[REDACTED]
[REDACTED]

36. Medical device customers do not typically negotiate pricing for commercialized devices unless and until a coating passes feasibility testing. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]; 562:5-22, 580:6-17 (de Freitas) (“pricing is ... irrelevant at that early stage [of testing]”).

37. Customers select a coating based on performance, not price. [REDACTED]

[REDACTED]; Welsh Dep. 93:4-9 (“My focus was always on performance and safety.”); Tr. 820:2-10 (Moran) (“Everything in the feasibility stage is predicated on performance.”).

38. The cost of a hydrophilic coating typically reflects only a small portion of the overall cost of a medical device. [REDACTED]

[REDACTED]; Tr. 1090:15-25 (Fix) (“The coating also makes up a really small portion of the cost of making the device[.]”); [REDACTED]

[REDACTED].

39. Customers do not typically play coating suppliers off of one another to obtain better pricing. Welsh Dep. 93:4-13 (“We never tried to play [Biocoat and Surmodics off] one another with regards to pricing.”); [REDACTED]

[REDACTED]

[REDACTED]

40. As further evidence that customers do not rely on head-to-head competition to get better prices, coating suppliers usually do not know which other suppliers (if any) a customer is considering. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] 817:3-14 (Moran) (same).

41. In addition to ensuring that a coating meets a device's performance needs, customers consider curing time and their own manufacturing processes and equipment in selecting a coating. Thermal coatings typically take longer to cure and cost more than UV coatings. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]; 1297:11-16 (Hance) ("[T]hermal requires 30 to 60 minutes of cure time. ... And that's just something that most people at scale are not willing to consider."); 1466:9-14 (Hergenrother) (thermal allows for larger batch sizes but takes longer). Because UV curing is faster, UV coatings are easier to apply at scale. Tr. 1297:17-21 (Hance) ("UV is faster, it's cheaper, less labor, and ... more conducive to scaling."); [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

42. A customer's investment in curing equipment also impacts its coating selection. Equipment for applying hydrophilic coatings is expensive, and OEMs that generally invest in either thermal or UV equipment cannot apply the other curing type without significant additional investment. DX-290.002 (explaining that a customer "could not justify switching out his investment in UV curing equipment [but] would be very willing to work with Biocoat if [it] had a UV curable hydrophilic coating"); Tr. 577:11-24 (de Freitas) (estimating \$250,000 for "low end, for R&D-level pieces of

equipment” and \$1.5 million for “fully automated inline systems”); [REDACTED]

[REDACTED]; Brenizer Dep. 44:24-45:6 (Teleflex prefers UV because “we have the equipment for UV”);

[REDACTED]; Johnson Dep. 22:10-15; Hiatt Dep. 33:3-13. All types of customers may have coating equipment to apply coatings in-house, not just larger customers. [REDACTED]

43. Even where OEMs have both thermal and UV equipment, they may have limited capacity for one of the curing methods, which will impact their coating selections. [REDACTED]

E. Competition To Coat A Medical Device Is Device Specific

44. The selection of a lubricous coating depends on the device to which it will be applied. Testing is required to determine whether a given coating will work on a particular device. Section II.E. [REDACTED]

45. Competition to coat a device also is device specific. Testing is required because when applied to one substrate (*e.g.*, metal), a coating may not have the same performance as when applied to a different substrate (*e.g.*, silicon). [REDACTED]; 311:8-19 (Petra); 1425:17-1426:4

(Hergenrother); Owens Dep. (July 15) 72:16-73:6; Jalgaonkar Dep. 39:1-12; Borgaonkar Dep. 70:23-71:15; Welsh Dep. 42:10-24.

46. UV and thermal coatings are not substitutes for all customers and all devices. Certain medical devices cannot use one coating type or the other because of their chemistry or geometry. As discussed above, UV light cannot reach the inner diameter of medical devices and is not an option for coating the inner diameter of catheters. Section II.A. [REDACTED]

[REDACTED] Dr. Fix's own data show the majority of customers use only UV or thermal coatings, but not both. Tr. 1578:15-1580:15 (Wong) (92.3% of customers use only one curing method).

47. Approximately 20% of Biocoat's revenue is attributed to devices requiring inner diameter coating. Tr. 576:11-23 (de Freitas); *see also* [REDACTED]; [REDACTED]; 1292:19-1293:2 (Hance) ("every outer diameter has an inner diameter" and "there's a very big market for inner diameter lubricity").

48. The *only* examples Plaintiffs provided of using UV to cure an inner diameter are

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

49. UV coatings will not work on certain substrates, including certain plastics, that deteriorate if exposed to UV light. Tr. 575:10-20 (de Freitas); *see also* [REDACTED]

50. Thermal coatings will not work on heat sensitive substrates, including balloons or other soft polymers. ¶ 18.

51. Even where both UV and thermal coatings might conceivably both be options at the outset of development, OEMs typically rule out one or the other due to performance at the feasibility testing stage. [REDACTED]

[REDACTED]; 485:22-486:2, 486:17-487:1 (Eccles) (agreeing Scientia turned to UV after thermal “didn’t perform as ... expected”).

52. Customers also view UV and thermal coatings as distinct products. Brenizer Dep. 45:22-25 (Teleflex “regards UV and thermal cured coatings as distinct product categories”); *see also id.* 101:12–14 (“The UV cures, in my experience, have different performance than the heat cures. And the heat cure, to me, is only if I can’t use a UV cure.”).

53. Because UV and thermal coatings are, in many cases, not substitutes, several coating suppliers have decided to develop both curing methods to meet customer demands. Biocoat developed a UV coating to add to its thermal offerings. Tr. 813:6-15, 816:21-23 (Moran); 1427:19-1430:22 (Hergenrother); DX-290.002; PX1344-009.

54. Harland recently added a thermal coating alongside its UV line, and [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] None of Biocoat, [REDACTED]

[REDACTED]

[REDACTED] Tr. 816:2-5 (Moran); [REDACTED]

[REDACTED]

55. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

56. A former Biocoat employee, Dhruv Patel, commented in an interview that UV and thermal cured coatings are “interchangeable,” but Mr. Patel testified under oath that that statement was “not accurate” because “[t]here are certain applications ... where UV will not work.” D. Patel Dep. 161:21-162:5. Mr. Patel further explained that “whether UV or thermal is an option” for a given medical device, “[d]epends on the specification from the customer.” *Id.* 162:12-14, 162:16-17.

F. Once A Medical Device Receives FDA Approval, Switching Coating Suppliers Is Commercially Infeasible

57. A coating selected for an FDA-approved and commercialized medical device typically remains on the device for the device’s lifetime, which can be decades. Tr. 810:12-22, 811:5-7 (Moran) (Biocoat has been applying the same coatings to the same medical devices for “upwards of 20 or 30 years”); [REDACTED]

[REDACTED] DX-736.250, .389-.392 (Wong Rep.) (showing Biocoat customers and Surmodics projects that are over 20 years old and still use the same coatings).

58. Once the FDA approves a medical device with a coating, it is commercially infeasible for the device maker to change coatings, as doing so would require re-testing and re-submitting the device to the FDA for approval. Tr. 510:14-18, 556:13-16 (de Freitas) (changing coatings on a

commercialized device “would require a new clearance from the FDA, so it would be like starting over on the device and potentially risking it commercially”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Welsh Dep. 162:17-163:120 (“[W]e’re not in the business of changing coatings based on price because there is extensive testing and refile with not just the FDA ... it’s just not something you can just change ...”).

59. Once a coating is selected for an FDA-approved device, customers are essentially “locked in” to their coating selection. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 811:13-15 (Moran) (“[O]nce our hydrophilic coating is on a device that is 510(k) approved by the FDA, it never comes off. They never change the coating on that device.”); [REDACTED]

[REDACTED]

[REDACTED]; 1540:25-1541:6 (Wong) (“[O]nce that device gets FDA approval, it’s locked in and it doesn’t switch. It’s no longer under competition.”).

60. [REDACTED]

61. There is no evidence in the record of any medical device customer ever changing coatings on an FDA-approved and commercialized device, and witnesses repeatedly testified that they were not aware of any instances where a medical device customer had switched coating suppliers on an FDA-approved device. Tr. 563:13-22, 588:20-21 (de Freitas); [REDACTED] 1440:1-9 (Hergenrother). [REDACTED]

62. Biocoat adopted a sales strategy for a brief period of time, during which it attempted to persuade OEMs to switch coatings on commercialized devices, but that strategy was unsuccessful and failed. Tr. 821:19-822:19 (Moran) (strategy was abandoned after “[l]ess than a year” because Biocoat was “losing opportunities, not gaining” any); Tr. 567:3-568:11 (de Freitas) (strategy to win commercialized devices failed); DX-248.004.

63. [REDACTED]

G. Commercialized Medical Devices Are Governed By Long-Term Agreements

64. Pricing for coating commercialized medical devices is typically governed by long-term agreements. [REDACTED]

[REDACTED] 533:19-24, 585:5-8 (de Freitas) (15 years is standard); 348:5-8 (Ventura) (“Our partnerships often span 15 to 20 years.”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

65. These long-term agreements lay out price terms, including annual price increases (which typically track indices, like inflation, and are capped), and royalty payments if applicable. Tr. 585:21-586:4 (de Freitas); [REDACTED]

66. [REDACTED]

[REDACTED]

67. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

H. The Vast Majority Of The Parties' Current Revenues Come From Contracts Won Years Ago From Coatings That Are No Longer Marketed

68. The revenue that a coating supplier earns from a medical device depends on the success of that medical device, which is unknown at the time the coating is selected. Tr. 811:5-15, 823:22-824:7 (Moran) (agreeing that “it’s the success of the medical device that determines the success for Biocoat at the end of the day”); [REDACTED]

[REDACTED] Tr. 1616:5-1617:8, 1618:15-1621:21 (Wong) (discussing Appendix 3 of his Report, DX-736.237-254, which analyzes the industry’s revenue cycle, finding “significant rates of failure and attrition among devices” and “great variability” in success of devices among large and small competitors, such that “it’s effectively luck at the point where competition occurs”).

69. In 2024, more than 90% of Biocoat's commercial revenues came from customers first contracted more than five years ago. Tr. 1543:2-1544:7 (Wong) (discussing DX-736.395 (Wong Rep.)); Tr. 589:11-591:1 (de Freitas); 1307:23-1308:8 (Hance) (90% of Biocoat revenue "predates five years or more" and more than half dates from three neurovascular start-ups).

70. The same is true of Surmodics's revenues. In 2024, more than 99% of Surmodics's commercial revenue came from device projects that Surmodics won more than five years ago. Tr. 1544:22-1545:12 (Wong) (discussing DX-736.396 (Wong Rep.)).

71. Biocoat's legacy coatings are not offered to new customers and therefore are not used to compete for new business. Tr. 587:18-588:12 (de Freitas) ("[W]e don't train any of our engineers to even support those legacy materials."); [REDACTED]

72. Biocoat's legacy coatings frequently employ older technology, are inferior in quality relative to today's coatings, and can have much longer curing times. Tr. 1450:15-1451:2, [REDACTED] (Hergenrother); 887:18-888:10 (Marker).

73. It is only in rare instances that current customers already using a legacy coating on a device may wish to test a legacy coating on a new device, because they are familiar with that coating. [REDACTED]

[REDACTED] But Biocoat does not offer legacy coatings to new customers. [REDACTED]

74. Revenues from legacy coatings do not reflect current competition. Tr. 1450:8-1451:12 (Hergenrother) ("The legacy coating products play no role in our working with current -- with new customers and applying coatings to their devices. We don't use them. ... these are ones that have been -- been used, probably been introduced onto the market by our customers 10-plus years ago. They're not a factor in what we're offering today."); [REDACTED]
[REDACTED]; 1312:7-1314:14 (Hance) (Only 10% of revenue "will be reflective of current competition.").

75. In particular, because of the nature of these legacy revenues, revenue-based shares are biased towards older companies, which have accumulated more legacy revenues over time. Tr. 1540:2–9 (Wong) (explaining that legacy revenue “far overstate the [current] competitive significance ... of Biocoat and Surmodics” as they “are the two oldest firms in this industry”).

III. THE PROPOSED ACQUISITION OF SURMODICS AND DIVESTITURE TO INTEGER WILL BENEFIT CUSTOMERS AND ENHANCE COMPETITION

76. On May 28, 2024, Surmodics entered into a Merger Agreement with BCE Parent, LLC and BCE Merger Sub, Inc. Surmodics, Inc., Form 8-K, SEC File No. 0-23837, Ex. 2.1 (May 28, 2024) (hereinafter the “Merger Agreement”).¹ GTCR LLC is not a party to the Merger Agreement. *Id.* There is no evidence that GTCR LLC holds any of BCE Parent’s or BC Holdings’s assets [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

77. GTCR LLC does not control BC Holdings. Rather, GTCR LLC is an investment adviser to private equity funds. Tr. 869:1-7 (Marker). In that role, GTCR LLC provided investment advice to the Strategic Growth Fund regarding the proposed acquisition of Surmodics. *Id.* 871:11-23 (investment team presents due diligence findings to investment committee for funds making investment); [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] Again, there is no evidence that GTCR LLC (as opposed to the Strategic Growth Fund) holds any interest (let alone a controlling interest) in BC Holdings.

¹ Surmodics’s Form 8-K is publicly available at <https://www.sec.gov/Archives/edgar/data/924717/000119312524148609/d842139dex21.htm>. SEC filings are “matters of the public record” and thus subject to judicial notice. *See Gavin v. AT&T Corp.*, 2004 WL 2260632, at *1 (N.D. Ill. Sept. 30, 2004).

A. BC Holdings Is Acquiring Surmodics To Build A Broader Platform For Customers And Become A “One-Stop Shop” For Medical Device Customers

78. In recent years, Biocoat has grown to become a full-service hydrophilic coatings company with complementary coating products and services. PX1344-008, -054-056. Biocoat developed UV coating as a complement to its thermal coating offerings. ¶ 53.

79. BC Holdings’s and Biocoat’s M&A strategy is not to anticompetitively consolidate hydrophilic coating providers, but rather [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. 1286:12-25 (Hance) (“[A]dd[ing] adjacent

capabilities to a company to make them more relevant for the medical device industry is ... a core part of the proposition.”); 1305:18-1306:1 (“Q. Did any of that strategy involve acquiring companies to consolidate competitors? A. No. Q. What did it mean? A. Well, it meant, ... looking at the core company capability and then seeing near-term biomaterials businesses that would enable a more complete offering of ... a specialist biomaterials provider to the medical device industry.”); 880:14-

24 (Marker) (“[W]e saw opportunity to invest behind additional technologies that were complementary to largely the same customer base and provide some real benefits to customers.”).

80. Biocoat’s CEO, Mr. Hance, identified “a major gap in the sophistication of the supply chain for biomaterials,” as the currently fragmented supply chain is a vulnerability for customers. Tr. 1289:17-1290:4 (Hance). Consolidating the capability to provide hydrophilic, hydrophobic, and other coating capabilities along with complementary biomaterials asset capabilities benefits customers by providing [REDACTED]

Biocoat’s goal is to “become an effective ... one-stop shop with the technical capabilities that would be relevant for ... a medical device manufacturer and, ... to become a strategic partner to those very companies.” Tr. 1284:23-1285:13 (Hance); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Biocoat “see[s] Surmodics as “an extension of [its] biomaterials initiative.” Tr. 880:14-881:13 (Marker); *see also id.* 879:2-5 (Acquisition of Chempilots is “a good example of expansion ... into broader biomaterials” platform “outside of coatings.”).

81. Surmodics began to explore strategic alternatives, including a sale of the company, starting in late 2022 due to cash constraints and its belief that its public shares were undervalued. Tr. 1027:3-1028:14 (Maharaj). The selection of Biocoat as a purchaser reflected the companies’ similar missions to improve patient outcomes and offer medical device customers a “[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

82. BC Holdings considered acquiring other hydrophilic coating companies prior to its decision to acquire Surmodics, but if this acquisition occurs, BC Holdings does not intend to acquire any other hydrophilic coating suppliers. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

884:6-11 (Marker)

(“There’s no intention to acquire other hydrophilic coaters.”).

B. The Divestiture To Integer Creates A New Hydrophilic Coatings Competitor

83. Although Defendants do not believe that the Original Transaction would substantially lessen competition in any market, BC Holdings agreed to divest Biocoat’s UV business, currently marketed thermal coatings, and related assets along with key employees to Integer in response to the FTC’s concerns and in an effort to resolve this litigation. DX-281.002; Tr. 884:12-19, [REDACTED]

84. BC Holdings put forth a divestiture package and a well-qualified buyer, Integer, that will create a new hydrophilic coatings competitor. Tr. 1528:4-20 (Wong) (“[T]his divestiture, it’s quite unique. It’s both a very strong, well-qualified buyer and a very strong divestiture package, and it creates a very large and what will be, I believe, a very effective competitor.”); 1325:11-1326:11 (Hance) (explaining his involvement in the successful divestiture of assets to Abbott as part of Boston Scientific’s acquisition of Guidant and how he leveraged that experience here to identify Integer as a strong divestiture buyer); *see also* Tr. 1329:11-1330:4, 1330:12-21 (Hance).

85. Through the Divestiture, Integer is acquiring the UV and thermal coatings that Biocoat actively markets, along with the corresponding FDA master files for the divested products, Biocoat's brands (Biocoat and HYDAK), the Witmer facility and equipment, transition services, and 11 full-time employees, including a PhD polymer chemist (the only specific role Integer requested) who helped invent Biocoat's UV coatings, Dr. Tyler Long. *See* PX1627-003-004; Tr. 886:7-892:3 (Marker); 1412:7-21 (Hergenrother); [REDACTED]

[REDACTED]

86. The Divestiture includes a license-back of the thermal coatings from Integer (who will own all of the IP and know how) to the merged firm so that both the merged firm and Integer will compete to sell thermal coatings, creating a new thermal competitor. Tr. 888:18-889:7 (Marker); DX-002.33-.34 (§ 6.03(a)); Tr. 1536:19-1537:9 (Wong) ("The divestiture actually creates more competition. It gives two different firms post-transaction thermal products. And that's more than existed today. And that's actually a boon for competition."); Tr. 605:13-606:2 (de Freitas) ("[F]or thermal [the license back] adds a competitor, so it increases the competitive landscape ... I think there's more companies that will be directly supporting the medical device OEMs and the start-ups with -- with all those technologies than there is today."); 1740:3-13 (Senn) ("This is, essentially, why we are pursuing the divested assets, so [Integer] can compete within a space that we haven't previously participated."); DX-736.043 (Wong Rep.) ("[T]he proposed transaction causes the market to gain a new entrant, resulting in an expansion from the three coating options offered by Biocoat and Surmodics (Hydak Thermal, Hydak UV, and Surmodics's UV) to four post-transaction options (the same plus an extra option identical to Hydak Thermal)."); Tr. 883:19-25 (Marker). Biocoat's CEO, based on his similar experience with a license back arrangement in a previous divestiture, expects that Integer and the merged entity initially having the same thermal coatings will lead them to

“compete intensively both commercially as well as from an R&D perspective.” Tr. 1338:7–1339:5 (Hance); *see also* 1452:4-19 (Hergenrother) (“I have no doubt that [Integer] will be very creative and innovate” while initially selling the same thermal coatings under the license back.).

87. Plaintiffs surely will cite an interview with Dhruv Patel, a former Biocoat employee, in which he stated that, after the proposed transaction, customers “will not have [the] option to look at alternatives” to Surmodics’s royalty model. D. Patel Dep. 123:5-23. However, Mr. Patel testified that at the time of the interview, he did not have any personal knowledge of the parties’ business plans, and his quote was just “speculation.” *Id.* 157:6-15. Mr. Patel also clarified that “[w]ith [the proposed] divestiture,” there “will definitely be a competitor in the market, and ... will be another option.” *Id.* 124:11-125:4.

88. The Divestiture agreement is signed and will become effective upon the closing of the Original Transaction. [REDACTED] There is no scenario in which BC Holdings acquires Surmodics but the Divestiture does not take place. [REDACTED]

89. Contrary to Plaintiffs’ submission, the Divestiture was not “last minute.” Tr. 895:17-897:14 (Marker). The time to finalize and execute the Divestiture reflects that: (1) Integer is a serious buyer that conducted thorough due diligence and engaged in arms-length negotiations to arrive at the deal terms, *id.* 897:15-898:5; and (2) BC Holdings wanted to give the FTC the opportunity to weigh in before the agreements were executed, *id.* 895:17-897:14. The final terms for the Divestiture are materially identical to those presented to the FTC in May. *Compare* DX-281.009-.010 (May 6, 2025 “Surmodics/Biocoat Divestiture Proposal”) (identifying components of the Divestiture package, including Biocoat UV, Biocoat thermal, A14 and G-23 thermal coating, Biocoat/HYDAK brand, qualified manufacturing facility, coatings equipment, and coatings personnel), *with* PX1627-003-004 (May 28, 2025 Term Sheet) (identifying tenets of the term sheet, including Biocoat UV, Biocoat

thermal, A-14 and G-23 legacy thermal coating, Biocoat/HYDAK brand name, Witmer Road facility, equipment, personnel, and support required for transition), DX-284.004 (June 11, 2025 FTC presentation) (outlining similar terms), and [REDACTED]

C. Integer Is Uniquely Situated To Compete Immediately And Has Everything It Needs To Do So

1. Integer Is A Strong, Well-Positioned Buyer With Over 20 Years Experience With Hydrophilic And Other Coatings

90. Integer is a leading contract development and manufacturing organization (“CDMO”) that services the medical device industry. Tr. 1717:16-24 (Senn). A publicly traded company with \$1.7 billion in revenue in fiscal year 2024 and 11,000 employees, Integer is much larger than Biocoat and Surmodics combined. *Id.* 1717:25-1718:4, 1716:8-13; 1529:15-24 (Wong).

91. Integer supports OEMs by making components, subassemblies, and finished devices. Tr. 1731:8-18 (Senn). Integer has strong relationships with customers, including Medtronic, Abbott, and Boston Scientific. *Id.* 1716:8-18 (Integer supports the entire medical device industry); *id.* 1717:16-24 (Integer has strong relationships with its customers and has “developed a reputation as being a leading provider of both contract development and manufacturing.”); [REDACTED]

[REDACTED]

[REDACTED]

92. Integer has over 20 years of experience applying hydrophilic coatings, both UV and thermal, to medical devices. Tr. 1718:24-1719:9, 1719:19-24 (Senn). Integer applies hydrophilic coatings to more than two million devices each year. *Id.* 1719:25-1720:3. Of its over 30 R&D and manufacturing facilities across the globe, Integer applies hydrophilic coatings to devices in Chaska, Minnesota, as well as in Ireland and Mexico. *Id.* 1718:13-17, 1720:21-1721:1; DX-107.005.

93. Integer has equipment to apply different types of hydrophilic coatings to devices, and has 20-plus years of experience testing hydrophilic coatings to determine whether a coating meets a

customer's specifications. [REDACTED]; Tr. 1720:4-9 (Senn) ("Q. Does Integer have all the equipment to apply all of the different types of coatings to devices? A. Yes. In some cases, we purchase that equipment from coating equipment suppliers. In most cases, though, we have designed that equipment in-house and developed those processes internally and they're proprietary to Integer."); *id.* 1720:10-15 ("We have extensive experience in proprietary test methods that we've used for the last 20-plus years to evaluate hydrophilic coatings against one another.").

94. Integer employees have experience with the chemical makeup of hydrophilic coatings and how the coatings interact with the substrates of devices. *Id.* 1720:16-20.

95. Integer also has employees with prior work experience selling hydrophilic coatings, including at other outsourced hydrophilic coating providers like Harland. *Id.* 1721:2-15; 600:2-23 (de Freitas) (Dhruv Patel, a former Biocoat and current Integer employee, was involved in developing customer relationships at Biocoat that are being transferred to Integer in the Divestiture and is "probably one of the most technical savvy people in hydrophilic coatings").

96. Integer has been manufacturing and applying other lubricious coatings (*e.g.*, hydrophobic coatings) for over 40 years as part of its CDMO business. Tr. 1719:10-18 (Senn) ("A. [W]e've manufactured and applied hydrophobic coatings for over 40 years. It's a technology that we rely on for a number of products. And we have a lot of expertise when it comes to both the formulation and the application of hydrophobic coatings."); [REDACTED]

97. In 2025, Integer acquired two companies in the medical coating space: Precision Coating, which manufactures hydrophobic coatings, and VSi Parylene, which focuses on conformal coatings. Tr. 1714:21-1715:10 (Senn). Integer now manufactures and applies hydrophobic and parylene coatings through these companies. *Id.* 1731:8-1732:2.

98. Integer has experience with the FDA approval process, with at least 28 of its own FDA-approved medical devices. Tr. 1650:7-1651:8 (Wong).

2. Integer Is Committed To A Strategy To Offer Coatings As A Service Offering, With the Goal To Be A “One-Stop Shop” For Its Customers

99. Since 2018, Integer has been implementing a strategy to expand its offerings to include medical device coatings. Tr. 1715:11-1716:7 (Senn) (“So, Integer developed our strategy back in 2018. It’s a market-based strategy. We have specific markets that we’re pursuing. They’re the higher growth markets within the industry. We want to treat unmet patient needs.”).

100. With the acquisition of Precision and VSi Parylene in 2025, Integer now offers standalone coating services, separate from its device manufacturing business. *Id.* 1731:8-1732:13 (“[W]hen we acquired Precision Coating and, subsequently, VSi Parylene, we bought unique capabilities, but we also -- it’s also a different business model. Historically, Integer’s business model is to make components or sub-assemblies or devices for our customers. It’s more of a manufacturing model, whereas the coatings model is more of a service model.”).

101. Integer’s commitment to implementing its coatings strategy is not speculative; since those acquisitions, Integer has been positioning itself in the market as a full-service coating platform. *Id.* 1727:18-1729:14; DX-107.007; Tr. 1532:17-1533:6 (Wong) (Integer’s prior acquisitions “is an indication of a long-term committed strategy to compete in this space.”); *see also* Tr. 592:21-593:6 (de Freitas) (Integer “created a coating center of excellence and positioned themselves as the experts in coating,” meaning “[t]hey’re marketing as a services organization to allow companies to send devices to them to get their various lubricious coating needs.”).

102. Integer does not presently manufacture hydrophilic coatings and views that as a strategic gap in its offerings. Tr. 1727:18-1729:14 (Senn) (Hydrophilic coatings are “central to [Integer’s] strategy to develop as many capabilities as possible ... to better serve our customers, because our

customers are looking for larger, more capable suppliers to partner with.”). The Divestiture provides Integer with the opportunity to fill that gap and better serve its customers. *Id.* 1723:11-16 (Hydrophilic coatings “fills an important capability gap for us. And we feel like we can better serve our customers if we have the ability to both formulate, as well as apply hydrophilic coatings.”); *see also id.* 1729:15-22, 1727:18-1728:11 (“[I]t’s a high-value, high-technology part of the value chain that we think our customers would look to us to develop and manufacture products for them.”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. 1533:7-14 (Wong).

103. Integer wants to create more touchpoints with its OEM customers and become a one-stop-shop for its customers. DX-107.010 (“The Divestiture Assets Fill A Strategic Gap ... Positions Integer as ‘One-Stop-Shop’ for Coatings/Surface Modification”); *see also* Tr. 1727:18-1729:14, 1734:5-13, [REDACTED]

[REDACTED] Tr. 1533:18-1534:5 (Wong).

104. Integer previously developed its own hydrophilic coating, but in its view the product it developed was not differentiated enough to succeed commercially. Tr. 1774:10-1775:11 (Senn). The Divestiture will enable Integer to fill its gap immediately with an already proven product. *Id.* 1742:4-16 (“I think Biocoat, obviously, has a well-known brand, a reputation for producing high-quality, high-performance coatings. [Biocoat also] knows how to produce coatings at scale; and, as part of the [TSA], they would teach us how to produce these coatings at scale. So, I think the two primary barriers of why we cancelled the project are, essentially, mitigated through the agreement that we have with Biocoat.”).

3. Integer Offers Benefits To Customers That The Merged Biocoat-Surmodics Entity Will Not

105. Although the merged entity initially will sell the same thermal coatings as Integer pursuant to license back, Integer is confident that it will be able to compete because it offers “other value propositions that the coating companies don’t have.” Tr. 1746:18-25 (Senn). With a hydrophilic coating offering, in addition to its hydrophobic coatings and parylene offerings, Integer will provide customers with a broader range of offerings than the merged entity. *Id.*; Tr. 597:14-19 (de Freitas) (Integer’s “coatings business today is more diverse. [Biocoat has] one technology or one platform that has two technologies within it on hydrophilic, but they have multiple material options.”).

106. Integer already has contracts with OEMs that, in certain instances, have financial incentives to do more business with Integer. Integer’s customers can use existing contracts with Integer rather than separately negotiating contracts with different hydrophilic companies and managing multiple suppliers. Tr. 1735:3-19, [REDACTED]

[REDACTED] Customers can leverage Integer’s expertise in different areas to accelerate their time to market for their devices. *Id.* 1728:12-22 (“Another benefit that our customers get is that it ... helps them speed their time to market because we have specific expertise in these process areas. They can leverage our expertise to de-risk their programs and help get their products to market faster.”).

107. Integer has approached its existing customers with its hydrophobic coatings services since its acquisitions of Precision Coating and VSi Parylene. Those efforts have been successful, and Integer continues to gain traction including with non-traditional customers. DX-107.008 (“Expanding beyond core CDMO base, leveraging new coatings and surface modification capabilities to engage non-traditional component customers with stand-alone offerings.”); *see also*

Tr. 1731:8-1732:13, 1732:14-22 (Senn) (“We continue to gain traction as we integrate. But there has been no concern raised by those customers that we are now the owner of that business.”).

108. Integer is not concerned that customers will not want to purchase coatings or coating services because Integer may also compete in manufacturing medical devices. It is common for companies in the industry to be both suppliers and competitors. Tr. 1735:8-19, 1785:4-11 (Senn).

109. Surmodics itself is an example of a medical device manufacturer that also is a successful supplier of lubricious coatings. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

110. Integer also intends to expand beyond its core customer base, leveraging new coatings and surface modification capabilities to engage non-traditional component customers like other CDMOs and emerging start-up companies like Biocoat’s customers. Tr. 1731:8-1733:5 (Senn).

111. [REDACTED]

[REDACTED]

112. Integer is confident in the future revenue potential of Biocoat’s divested assets. Tr. 1761:24-1762:9 (Senn) (“I think this business has the potential to produce very positive returns to Integer. The hydrophilic coatings space is generally, you know, fairly profitable and would benefit our overall ... financial position. I think that’s the reason why we’re doing this acquisition.”). Although the acquisition of Biocoat assets is profitable for Integer without its selling coatings to any new customers, Integer intends to grow the hydrophilic coatings business further, benefiting

Integer's shareholders and customers. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *id.* 1761:8-23 (“Our intention, when we buy a company, is to grow that business and offer more capabilities to our customers. If we just ... focused on our internal supply, it wouldn’t be meeting our investment criteria for spending this type of money. And this is our shareholder ... money. We need to make sure there’s a good return and that we’re positively impacting our customers by doing it.”).

4. Integer Is Experienced In Acquisitions and Integrating Operations

113. Integer has a long track record of growing its business by acquiring and integrating complementary businesses to provide better services to customers. Since December 2021, Integer has gained new capabilities through its acquisition of various companies in the medical device space, including Oscor, ARAN Biomedical, InNeuroCo, Pulse Technologies, Precision Coating, and VSi Parylene. DX-107.007; Tr. 1727:6-1728:8 (Senn) (confirming success in integrating past six acquired companies). These acquisitions reflect Integer’s strategy to develop as many capabilities as possible to serve customers through their product lifecycle and also demonstrate Integer’s experience and ability to successfully integrate new assets and products.

114. Andrew Senn, who has worked at Integer for 18 years and has extensive experience with Integer’s experience applying hydrophilic coatings, is responsible for overseeing the integration of Biocoat’s divested assets post-transaction. Tr. 1712:13-1713:13 (Senn). Mr. Senn started in 2003 as a technician for Lake Region, Integer’s predecessor and, coincidentally, Biocoat’s first customer. *Id.* 1712:13-1713:13; Tr. 565:13-21 (de Freitas). For six years, he worked in a variety of R&D roles, including engineering and program management, where he was involved in the selection and qualification of coatings. Tr. 1712:13-1714:12 (Senn). After a brief period at St. Jude Medical from

2009 to 2013, Mr. Senn returned to Lake Region as the head of the R&D group, and from 2013 to 2017, he oversaw the development of guidewires, catheters, and introducers that used hydrophilic coatings. *Id.* 1712:13-1714:12. From 2017 to 2022, Mr. Senn worked in a sales and marketing role, and in 2022, he moved to a corporate role, responsible for mergers and acquisitions as well as investor relations and strategy. *Id.* 1712:13-1714:13. As the President of Integer's Cardio & Vascular division as of January 2025, Mr. Senn has been responsible for growing the division, which accounts for 60% of Integer's business and \$1.1 billion dollars of revenue, with about 6,000 employees. *Id.* 1714:13-20. In this role, he has overseen the acquisition of both Precision Coating and VSi Parylene. *Id.* 1714:21-25.

115. In addition to Mr. Senn, more than 30 deal team members at Integer have been involved in conducting diligence of the Biocoat assets. [REDACTED]; Tr. 1763:6-1764:3 (Senn).

116. Dhruv Patel, Principal Technical Sales Engineer at Precision Coating who previously worked at Biocoat for 15 years, has also participated in the diligence of Biocoat's divested equipment and facilities. [REDACTED]; D. Patel Dep. 10:7-15, 16:17-19, 29:11-17; Tr. 564:4-565:8 (de Freitas) (Mr. Patel was the "historian" at Biocoat who knows Biocoat's first customer accounts).

117. Integer conducted significant due diligence into the acquisition. Tr. 1764:18-1765:18 (Senn) ("[T]his was sufficient diligence time. ... [D]iligence is always fast, but we never cut corners."). Mr. Senn also was already familiar with the company because Integer conducted initial diligence on Biocoat in 2022, and Integer has been a customer for over 20 years. *Id.* 1764:18-1765:18.

118. Integer made over 280 diligence requests of Biocoat for documents and responses to specific questions, had two on-site visits, and conducted eight dedicated sessions where the respective functional groups at Integer and Biocoat connected to discuss and address Integer's specific questions. [REDACTED]; Tr. 1763:14-1764:4 (Senn).

119. Integer conducted due diligence of Biocoat's assets for several months, which is a standard timeline for a transaction of this size. Tr. 895:17-898:5 (Marker). By contrast, Integer conducted due diligence for one and a half months for the \$28 million acquisition of VSi Parylene, which was a relatively larger transaction. Tr. 1764:18-1765:18 (Senn). Integer has had more than sufficient time to fully diligence the assets that it is acquiring from Biocoat. *Id.*

5. Integer Will Be Able To Compete On Day One

120. Integer is receiving from Biocoat the assets that it needs to manufacture, innovate, and sell UV and thermal hydrophilic coatings and compete on Day One, and it does not require any other assets to successfully compete. Tr. 1760:9-12 (Senn) ("Q. Are there any assets that Integer is not acquiring, that it believes are necessary for Integer to compete effectively in providing hydrophilic coatings? A. No."); 1530:6-22 (Wong) ("This is really all the inputs Integer needs to complete the picture and be an effective competitor.").

121. **Facilities.** Integer plans to produce the coatings it acquires from Biocoat at its FDA-qualified facility in Chaska, Minnesota, which has been applying UV and thermal hydrophilic coatings for over 20 years. Tr. 1752:7-13, 1753:12-14, 1756:10-23 (Senn). The Chaska facility, with over 50 years of operation, has scalable manufacturing infrastructure and employs nearly 800 associates, including chemical engineers. *Id.* 1720:16-1721:1, 1752:7-25.

122. Integer has qualified hundreds of customers' medical devices for FDA approval out of its Chaska facility and is confident of its ability to qualify Biocoat's equipment and coatings in-house to be a vertically integrated part of Integer. *Id.* 1753:23-1755:18, 1756:16-23. Integer regularly qualifies new products from its facilities following acquisitions. *Id.* 1727:6-1728:8, 1748:13-1749:4 ("Integer generally has the knowledge and skill set to transition technologies between facilities, which, I think, is core to the integration of this product. ... I think we have all the pieces we need to successfully integrate these assets into our business."); *see also* DX-107.007.

123. Integer estimates that it will take approximately six months to set up Chaska to produce the divested coatings. During that time, Integer will leverage the Transitional Services Agreement (“TSA”) to market and sell coating manufactured by Biocoat. Tr. 1756:24-1757:16 (Senn).

124. Integer has already started to make facility improvements to enable the transfer of Biocoat equipment, and it has identified subject matter experts in Chaska to qualify relevant processes. Tr. 1757:17-23 (Senn) (“We’ve started to prepare. We’ve prepared the wet lab area. We are in the process of cleaning that up and making sure we have sufficient space for the equipment. We’ve also identified some subject matter experts in Chaska, that can be immediately available to work with the Biocoat team, to qualify those processes.”).

125. Integer does not believe there will be any interruption in services for Biocoat’s current customers following its acquisition of the Biocoat assets. Tr. 1757:24-1758:3 (Senn).

126. **Personnel.** In addition to the 11 employees included in the Divestiture, Biocoat offered to include two additional employees, but Integer does not need more, nor did it ask for more. [REDACTED]

[REDACTED] These employees, including two talented application development engineers, are trained in both UV and thermal coatings. Tr. [REDACTED] 1446:24-1450:7 (Hergenrother) (explaining qualifications of the transferring engineers and rebutting Plaintiffs’ assertion that the Divestiture cannot succeed without him). At Integer’s request, Biocoat has agreed to transfer Dr. Tyler Long, a polymer chemist skilled in developing new coatings, [REDACTED]

[REDACTED] 1444:2-1446:19 (Hergenrother) (Dr. Long is “a very talented and creative chemist” who “gets called in on helping ... troubleshooting” production problems and interacts with customers.).

127. If any additional employees are required, Integer will redeploy employees from another part

of its business or hire additional employees. [REDACTED] Integer's Cardio & Vascular Division has 6,000 employees, including engineers, chemists, and salespeople who have extensive experience with coatings, including hydrophilic coatings. *Id.* 1718:2-6, 1720:16-1721:7. Integer has more than 500 employees who focus on R&D, many of whom have engineering and process expertise on hydrophilic coatings. *Id.* 1718:7-10, 1749:5-18 ("We have the engineering and process expertise to apply these coatings. So I would say that we need the paint, which is the divested assets, and we already have painters."); D. Patel Dep. 46:8-10, 46:14-15, 46:17-19, 47:11-9 (explaining why he is not concerned about the R&D employees Integer is receiving: "The products are fully launched and it's now on people like me to sell the products. It's already developed, so it's now all about commercial effort to launch the ... product. So it's about applications development engineers ..."). Integer also has a sales force that is already aware of the benefits of hydrophilic coatings and can sell them to its existing customers on Day One. Tr. 1725:25-1726:8 (Senn).

128. Integer will have the personnel to stand up the hydrophilic coating business and continue to innovate. Tr. 1748:3-12, 1802:6-19 (Senn) ("[W]e've looked at all of these CVs for the eleven employees. We've actually spoken with four of them; and, based on their CVs and the conversations, we feel that this is the appropriate group of people to help us integrate the business. I mean, obviously we will supplement with Integer resources; and, if we need to use external consultants, we will [And employee] risk is effectively mitigated through the language of the TSA.").

129. **Coatings.** Integer selected the coatings it wanted and is receiving the most up-to-date coatings from Biocoat; it does not believe Biocoat's legacy thermal coatings would serve the needs of Integer's customers from a process or performance perspective given that legacy coatings are considered "outdated and not state of the art." Tr. 1778:24-1779:5, 1793:1-4 (Senn) (Integer

“handpicked the coatings.”). [REDACTED]

130. [REDACTED]

131. *Customer Relationships.* [REDACTED]

132. *Transition Services.* The TSA was designed to ensure that Integer and Biocoat will work to transfer specific processes and qualify coatings at the Integer facility within one year, though Integer intends to complete the work within six months of closing. DX-002.010, .086, [REDACTED]

[REDACTED]; Tr. 1756:24-1757:16, 1759:6-9 (Senn) (“[T]he TSA does go for 12 months. ... So, we do have some buffer built in But our target is to have internal qualification within six months.”).

133. The TSA allows Integer to supply coatings manufactured by Biocoat to customers on Day One while Biocoat transitions the know how, technology, and equipment for Integer to produce

coatings on its own in Chaska. Tr. 1725:18-1726:8, 1736:21-1737:6, 1754:5-14, 1756:24-1757:16 (Senn); [REDACTED]

[REDACTED]

134. The TSA between Biocoat and Integer is a standard agreement in the context of an asset purchase agreement, and Integer has executed several TSAs in its recent acquisitions. Tr. 907:1-16, [REDACTED]

[REDACTED] 1759:21-1760:8 (Senn) (“So, it’s ... something we’re used to operating under, both on the buy side, as well as we divested our non-medical business last fall and we had ... a TSA that goes the other direction”); 1758:14-24 (Senn) (“This is our standard format for a TSA schedule. We’ve had TSAs with a number of our recent acquisitions”).

135. There is no evidence that Biocoat will fail to comply with its legally enforceable TSA obligations. Tr. 1759:10-20 (Senn) (“Q. ... [D]o you anticipate that Biocoat will follow through on its contractual obligations? A. I have no reason to believe they wouldn’t.”); 1349:5-11 (Hance) (“Q. ... Do you intend to fully perform the transition services in this divestiture? A. Absolutely, yes. No question about it.”). And Biocoat is financially incentivized to comply, as Integer will pay [REDACTED] of the purchase price to Biocoat only after the transfer and qualification condition has been achieved. DX-002.010 (APA “1.04(a) Contingent Consideration”); *see also* [REDACTED]

6. The Divestiture Purchase Price Reflects An Arm’s Length Negotiation

136. [REDACTED]

137. [REDACTED]

[REDACTED] The price differential reflects the fact that the divested Biocoat coatings represent 10% of Biocoat's revenues—that is, Biocoat's legacy coatings represent 90% of its revenues. Tr. 1307:23-1308:8, 1331:10-1332:9 (Hance) (“[T]he vast majority of the original acquisition I think ties to ... those annuities, ... those original products from ... more than a decade ago.”); [REDACTED]

138. The [REDACTED] also reflects Integer's bargaining power, given the dynamics created by the sale taking place in the midst of this litigation. Tr. 1331:10-1332:9 (Hance) (“It can't escape, though, the fact that ... you're in a lawsuit with the FTC, that ... the prospective buyers are going to factor that in and think they might get a good deal.”); [REDACTED]

[REDACTED]

[REDACTED]

7. Integer Will Be A Formidable Innovator And Competitor Going Forward

139. Integer intends to continue to innovate and plans to utilize the application engineering and technical employees and equipment at the divested Witmer facility for R&D. Tr. 1752:1-6 (Senn). Integer requested a polymer chemist with expertise in the specific chemistry of hydrophilic coatings to help develop Integer's proprietary hydrophilic coatings, and Biocoat agreed to transfer Dr. Long in response to that request. Tr. 1750:13-24, 1834:13-1835:4 (Senn).

140. Integer's track record of investing over [REDACTED] in R&D annually—[REDACTED]
[REDACTED]—demonstrates Integer's historical commitment to innovation. Tr. 1653:1-19 (Wong); DX-736.050-.051 (Wong Rep.).

141. Integer will be a formidable competitor to the merged firm. Tr. 1330:12-21 (Hance) (“I think Integer is an outstanding buyer ... [T]hey're committed to the space and have been putting their ...

resources against being successful.”); 1349:15-1350:5 (Hance) (“I think they will be a very formidable competitor. They’ve built a complementary set ... of coatings for the medical device industry with their recent acquisitions, and this ... will add to that. And they’ll be able to provide one-stop shopping. I think they have the greatest array of strategic relationships and partnerships with the large OEMs and ... start-ups in the medical device industry, and they’ll be able to leverage that successfully.”); 596:14-597:4 (de Freitas) (explaining why Integer is “going to be a formidable competitor within coatings”: “I think Integer has the customer base. So they’ve been in the industry for a long time. They’re well respected. ... They have the commercial team in the U.S. and internationally. They have the technical background. With recent acquisitions, ... they have shown that they’re very interested in services and supporting their customers with all coating related requirements for services. And then their marketing team I think is very impressive. They will have the insight in future generation[s] of products and the pipeline of activity for the large medical device OEMs.”); 602:24-603:4 (de Freitas) (“I think it’s going to be more competitive.”); 1766:23-1767:11 (Senn) (“Q. ... [D]oes Integer believe that it will be able to compete aggressively for opportunities with respect to both UV and thermal-cured coatings after the acquisition closes? A. Yes. Q. And does Integer intend to actively compete aggressively for opportunities with respect to both UV and thermal-cured coatings after this acquisition closes? A. Yes.”).

142. Customers, including Plaintiffs’ witnesses, testified that they would consider Integer as a hydrophilic coating supplier. Tr. 497:5-14 (Eccles) (“Q. And Scientia is willing to consider Integer as a coatings provider, right? A. Yeah.”); [REDACTED]

[REDACTED]

[REDACTED] Welsh Dep. 171:22-172:9 (“If, in addition to acquiring Biocoat’s UV coating, Integer also acquired Biocoat employees and a Biocoat

manufacturing facility, would that make Alembic more comfortable purchasing Biocoat's coating from Integer? A. ... [F]rom a work standpoint on our end, it would be a reasonable, acceptable solution. Q. ... [Y]ou would be comfortable purchasing Biocoat's UV coating from Integer if there was a sufficient knowledge transfer from Biocoat to Integer; is that correct? A. That's correct.”).

143. Even Dr. Fix admits that Integer will compete going forward. Tr. 1190:25-1191:6 (“I believe that Integer will—intends to manufacture the coatings and likely will—be able to, eventually.”), 1197:5-13 (Fix) (“Q. But you do believe that Integer intends to sell their coatings on a standalone basis outside the CDMO business, right? A. My memory is that Andrew Senn said that they intended to do that. I don't have a reason to doubt him.”).

IV. PLAINTIFFS FAIL TO DEMONSTRATE THAT “OUTSOURCED HYDROPHILIC COATINGS” IS A RELEVANT PRODUCT MARKET

A. Plaintiffs’ Alleged Relevant Market Is Inconsistent With “Commercial Realities” And Lacks Factual And Economic Support

144. Plaintiffs’ alleged relevant market is the market for “outsourced hydrophilic coatings” applied to all medical devices. That alleged market is inconsistent with commercial realities because it disregards how competition occurs and how customers choose a coating supplier for a particular device. Section II. There are at least three flaws in Plaintiffs’ proposed market:

145. *First*, Plaintiffs’ proposed relevant market is too broad because it includes both UV and thermal coatings for *all* devices, even though many customers can use only one or the other on a device due to the device’s substrate or geometry and/or the customer’s own curing equipment. Sections II.A, II.D-E. Even when customers test both UV and thermal on a device, frequently one or the other fails because of the differentiated chemistries of the coatings. Sections II.A, II.E. The general lack of interchangeability between UV and thermal is why Biocoat developed a UV coating, Hydromer is attempting to do the same, and Harland recently added a thermal coating. ¶¶ 53-54.

146. *Second*, the relevant market is too narrow because it excludes other coating substitutes, such

as hydrophobic coatings, lubricious additives, or devices made with slippery materials that require no coating at all. Section II.A, II.D-E. Plaintiffs' proposed market ignores evidence demonstrating that, in some instances, hydrophobic coatings are substitutes for a hydrophilic coating, particularly for certain guidewires and catheters. *Id.*

147. **Third**, Plaintiffs' claimed relevant market also is too narrow because it excludes "in-house" coatings. Section II.C. Whether companies that use in-house solutions have the capacity to enter the market as vendors for others is irrelevant; what matters is whether customers that use outsourced coatings can switch to in-house coatings, and the evidence demonstrates that many can. *Id.* For this reason, coating suppliers recognize that they compete with and lose sales to in-house coatings. *Id.*

148. As a byproduct of their attempt to criticize Dr. Wong's analysis of FDA opportunity data, Plaintiffs implicitly concede that many of the medical devices included in their proposed market could be coated with a hydrophobic coating or no coating at all. Tr. 1962:7-17 (Pls. Closing). In the public FDA data on which Dr. Wong relied, 77 of the 213 coating-eligible devices did not have the coating type specified. Tr. 1551:17-1554:2 (Wong). Plaintiffs claim that all but two of the 77 should be treated as having no hydrophilic coating at all. Tr. 1915:4-12 (Fix) ("Q. ... I heard you, in your direct testimony, say you believe none of the 77 devices has a hydrophilic coating. ... A. ... I don't think I said exactly that. Q. Okay. Is it none, or is it just fewer? A. My belief is that two out of the 77 have a hydrophilic coating.").

149. If Plaintiffs are correct, then close to 60% of all catheters and guidewires are using a hydrophobic or no coating at all as an alternative to a hydrophilic coating—which would mean that Plaintiffs' market definition fails because it does not include hydrophobic or no coating solutions as reasonably interchangeable substitutes for hydrophilic coatings. DX-736.189 (Wong Rep.); [REDACTED]

[REDACTED] But if

Plaintiffs are wrong, and in fact many (or even just 16) of the 77 devices have hydrophilic coatings, then Dr. Wong's opportunity data would result in combined shares for Biocoat and Surmodics of below 30%. Tr. 1916:5-16 (Fix). Either way, Plaintiffs' case fails.

B. The *Brown Shoe* Factors Do Not Support Plaintiffs' Market Definition

150. The commercial realities of the lubricious coatings industry confirm that the *Brown Shoe* practical indicia defeat Plaintiffs' proposed "outsourced hydrophilic coatings" market. Section II. The practical indicia reveal not only that UV and thermal coatings very frequently are not reasonably interchangeable, but also that in-house and hydrophobic coatings are reasonably interchangeable in many instances. *Id.* As discussed above, coating selection depends on the specific device and customer, a fundamental characteristic of the industry that Plaintiffs fail to take into account in defining their proposed market. *Id.*

151. **Peculiar characteristics and uses.** UV and thermal coatings have different underlying chemistries and applications. Section II.A. For many medical devices and customers, UV and thermal coatings are not substitutes. Sections II.A, II.D-E. UV coatings require a line of sight and thus will not work on the inner diameter of devices or those with similar challenging geometries, and thermal coatings will not work on heat sensitive materials. Section II.A. Even when customers test both UV and thermal on the same device, frequently one or the other fails. Sections II.A, II.D-E.

152. On the other hand, hydrophobic coatings have peculiar characteristics and uses that are reasonably interchangeable with hydrophilic coatings for some medical devices. Sections II.A, II.E. Even no coating can achieve the same characteristics depending on the device and clinical use. *Id.* Similarly, customers and suppliers consider in-house coatings as an alternative to third-party suppliers given the similar characteristics and uses. Section II.C.

153. **Industry and public recognition.** Many industry participants consider UV and thermal to be complementary products. ¶¶ 52-54. Suppliers in the industry also recognize that expanding their offerings to include both UV and thermal-cured coatings will help them secure new customers and opportunities without taking customers away from their existing offerings. *Id.*

154. Meanwhile, suppliers in the industry also recognize that there are other methods to achieving lubricity beyond hydrophilic coatings, such as hydrophobic coatings. Section II.A. And industry players recognize the competitive pressure that comes from in-house coatings. Section II.C.

155. **Distinct Customers.** Customers that have made significant investments in equipment to apply either UV or thermal coatings cannot use the other type of coating without making an additional investment, and they generally are unwilling to select the other type of coating. Section II.D. Dr. Fix's own data show the majority of customers use only UV or thermal coatings, but not both. Tr. 1578:15-1580:15 (Wong) (92.3% of customers use only one curing method).

156. Moreover, for certain customers, Plaintiffs' market not only includes products that are *not* reasonably interchangeable, but excludes alternatives that *are*. For example, a customer looking to coat an inner diameter may be more likely to consider PTFE or another hydrophobic material than a UV coating as an alternative to thermal. Sections II.A, II.D. And customers who have in-house coatings may turn to in-house as an alternative to outsourced coatings. Section II.C.

157. **Distinct Prices.** Thermal coatings are typically cured in a time-consuming batch manufacturing process that costs more, including due to higher labor costs, while UV coatings are cured in a quicker and cheaper process that is easier to scale. Section II.D.

158. **Specialized Vendors.** Many suppliers of hydrophilic coatings provide exclusively UV-cured or thermally-cured coatings. For example, [REDACTED]

[REDACTED]

[REDACTED]

159. **Unique Production Methods and Facilities.** Thermal and UV coatings also have different production methods because they are applied differently. Sections II.A, II.D. Thermal is cured with heat, while UV is cured with light. *Id.* This is an important difference for the many products where heat or light curing is not feasible. *Id.*

160. Plaintiffs also offer no evidence demonstrating that hydrophobic coatings are applied differently (*i.e.*, in a manner other than dipping or spraying), or that there is anything technologically unique about the production of in-house coatings that distinguishes them from outsourced hydrophilic coatings. Of course, there are certain customers of hydrophilic coatings that do not have in-house coatings. But for those who do have in-house options—such as device manufacturing giants [REDACTED]—there is no distinction for the purpose of assessing reasonable interchangeability. *See* Section II.C.

C. Dr. Fix’s Relevant Market “Analysis” Is Unavailing Because It Fails To Account For Heterogeneity In Demand Or Differentiation In Supply

161. Dr. Fix’s economic analysis does not save Plaintiffs’ purported relevant market. As numerous customers, competitors, and party witnesses testified, the coating selected for a medical device is customer- and device-specific. Sections II.A, II.D-E. In economic terms, that means demand for lubricious coatings is heterogeneous. Tr. 1571:25-1572:13 (Wong) (“And I think that specifically goes to the significant amount of heterogeneity in this industry. Again, we’ve heard every device is different; every device is going to be looking and has different parameters, different needs; and, then, is going to be subject to a different set of competition.”); DX-736.211-217 (Wong Rep.). Dr. Fix agrees that coating selection “could be device specific” and “depend on which device” a customer is developing, but he admits that [REDACTED]

[REDACTED]

162. Dr. Fix’s proposed relevant market does not account for this heterogeneity in demand. DX-736.142 (Wong Rep.); *see also* Tr. 1571:25-1572:13 (Wong) (“I think Dr. Fix’s market definition is too much of a one-size-fits-all strategy and it really just doesn’t capture that heterogeneity or variability ...”). It consists of hydrophilic coatings only, and excludes hydrophobic coatings, even though both can be options for the same devices (*e.g.*, guidewires). DX-736.143 (Wong Rep.); Tr. 1089:22-1091:8 (Fix); Sections II.A.

163. Even among hydrophilic coating suppliers, Dr. Fix’s proposed market includes only 15 outsourced coating suppliers, and excludes in-house coatings. DX-736.143 (Wong Rep.); Tr. 1534:21-1535:9 (Wong); [REDACTED] PX4000-142 (Fix Rep.). However, as Dr. Wong explains, it is highly unlikely that a customer would consider precisely these 15 suppliers’ coatings (no more and no less). DX-736.143 (Wong Rep.). Moreover, the evidence shows customers sometimes consider options outside of the 15 suppliers in Dr. Fix’s proposed market (*e.g.*, by including an in-house option, hydrophobic option, or no coating option). DX-736.143 (Wong Rep.); *see also* Section II.B.

164. Dr. Fix’s proposed market is overinclusive for certain customers and devices because he treats UV and thermal coatings as substitutes for most customers and devices. Tr. 1091:21-24 (Fix); PX4000-047 (Fix Rep.) (“UV-cured and thermal-cured coatings are viable alternatives for most customers and devices ...”). But Dr. Fix does not provide any quantitative support for this opinion. Tr. 1091:9-1092:17 (Fix); DX-736.158-159 (Wong Rep.). In fact, Dr. Fix admits that, contrary to his opinion, [REDACTED]

[REDACTED] and that, as Mr. de Freitas testified, “the ophthalmic portion of Biocoat’s

revenue,” which is a thermal-only inner diameter use case, comprises 20% of Biocoat’s sales. Tr. [REDACTED] *see also* Tr. 576:11-23 (de Freitas).

165. Indeed, there is ample evidence that UV and thermal coatings are not interchangeable for many devices. Sections II.A, II.D-E. Dr. Wong’s quantitative analysis showed minimal substitutability between UV and thermal coatings. His analysis found that [REDACTED]

166. While being overinclusive in some respects, Plaintiffs’ proposed market is underinclusive in other respects, as Dr. Fix leaves out options that customers turn to, such as hydrophobic and uncoated options. Dr. Fix provides no support for his opinion that customers will not substitute from hydrophilic coatings to hydrophobic or uncoated options. [REDACTED] Tr. 1090:15-1091:4 (Fix) (instead of conducting a quantitative analysis of cross-price elasticity or actual switching behavior, Dr. Fix relied on the assumption that device makers would not switch to hydrophobic coatings). And Dr. Fix ignores the many examples showing that customers do, in fact, consider those options. [REDACTED]

[REDACTED] Tr. 1575:7-1576:1 (Wong) (discussing examples “where a device has used hydrophobic material and hydrophilic coatings interchangeably”); *see also* Sections II.A, II.D-E.

167. Dr. Fix’s conclusion that customers will not substitute from hydrophilic to hydrophobic and uncoated options also is inconsistent with his submission that more than 50% of FDA-approved cardiovascular and neurovascular devices in 2024 should be excluded from his “outsourced

hydrophilic coatings” market. [REDACTED] 1896:12-24, 1898:22-1899:7 (Fix) (asserting that 77 out of 213 FDA-approved devices with no public disclosure of coatings likely had no hydrophilic coating, resulting in 122 of 213 devices (57%) with no hydrophilic coating); ¶¶ 148-49.

168. Further, Dr. Fix’s exclusion of in-house coatings is not based on any empirical analysis. Tr. 1093:23-1095:21 (Fix) (providing no empirical analysis for assertion that “I wouldn’t expect much substitution towards the in-source coating”); [REDACTED]

[REDACTED] By contrast, Dr. Wong testified that there are at least 19 different customers that use in-house coatings or are in the process of developing in-house capabilities, [REDACTED]

169. Dr. Fix’s proposed market is thus simultaneously over- and under-inclusive, and does not match the competitive realities of the industry. [REDACTED] Tr. 1571:25-1572:13 (Wong) (“I think Dr. Fix’s market definition is too much of a one-size-fits-all strategy and it really just doesn’t capture that heterogeneity or variability, and it doesn’t capture the true competitive dynamics for a good number of device opportunities in this industry.”).

D. Dr. Fix’s Hypothetical Monopolist Test Cannot Save Plaintiffs’ Market Definition

170. Plaintiffs also attempt to define a relevant market using a hypothetical monopolist test (“HMT”) as applied by Dr. Fix. The HMT is used to analyze whether a group of products is too narrow to constitute a relevant antitrust market. [REDACTED] The HMT asks whether (i) a hypothetical monopolist that controls that group of products could profitably raise prices by a small amount or, rather, (ii) too many customers would switch to other products, such that the lost sales would make the price increase unprofitable. *Id.* 1099:19-1100:9. If the price increase would be profitable, the group of products “passes” the HMT and can be considered a relevant market. *Id.*

Dr. Fix tested only the “outsourced hydrophilic coatings” market Plaintiffs pleaded in the Complaint.

[REDACTED]

171. Dr. Fix found that Plaintiffs’ proposed market of “outsourced hydrophilic coatings for U.S. medical devices” passed his HMT, and thus concluded that it is the appropriate relevant antitrust market to assess the effects of the merger. Tr. 1088:18-1089:9 (Fix). [REDACTED]

[REDACTED]

[REDACTED] When Dr. Fix’s version of the HMT is applied to additional market definitions—such as a thermal-only market, or a market containing only Surmodics and one other non-merging supplier—those markets also “pass.” Tr. 1580:18-1581:16 (Wong) (“Q. ... [D]o you believe that Dr. Fix’s hypothetical monopolist test has any predictive value? A. As he’s applied it in this case, no. ... [R]eally it effectively says every market you could think of passes his formulation of the test.”). All of these markets that pass Dr. Fix’s HMT are narrower than Plaintiffs’ proposed market. [REDACTED] Tr. 1580:21-1581:16 (Wong). Moreover, virtually any broader market would pass Dr. Fix’s HMT, including a market of all lubricious coatings (both hydrophilic and hydrophobic). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

172. The reason why Dr. Fix’s HMT malfunctions in this way is that it is not reliably constructed or applied. A key feature of the HMT is the substitution or “diversion” from products inside the candidate market to products outside the candidate market. PX4000-057 (Fix Rep.). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In this way, Dr. Fix assumed that, rather than tested whether, hydrophobic or in-house coatings should be excluded from the market. DX-736.164 (Wong Rep.); PX4000-060-061 (Fix Rep.).

V. PLAINTIFFS FAIL TO SHOW UNDUE CONCENTRATION IN ANY RELEVANT MARKET

A. Dr. Fix's Revenue-Based Market Shares Are Unreliable And Biased

173. Even assuming the propriety of an “outsourced hydrophilic coatings” market, Plaintiffs fail to present reliable evidence that the merging parties’ shares rise to the level of competitive concern.

174. Dr. Fix’s market shares (with the combined firm having an approximately 60% market share) are based on suppliers’ revenues, which largely come from legacy sales. Tr. 1084:15-1085:12 (Fix) (discussing PX4001); Section II.H. As Dr. Wong explained (DX-736.174-.175 (Wong Rep.)), the core flaws with Dr. Fix’s revenue-based market shares are:

- (a) they include legacy coating products that are no longer offered to new customers;
- (b) they are arbitrarily biased by wins earned many years ago;
- (c) they are arbitrarily biased by timing and “luck” associated with medical device commercialization—which devices succeed and which do not—that has little to do with coating suppliers;
- (d) they inherently ignore important customer choices, namely in-house coatings and uncoated designs (which have no recorded revenue), as well as hydrophobic coatings (which are not included in Dr. Fix’s calculations);
- (e) they do not (and cannot) accurately reflect Dr. Fix’s own purported relevant geographic market because Dr. Fix made arbitrary allocations of revenues based on where each customer’s medical devices are sold; and
- (f) they are necessarily biased by incomplete discovery.

175. Dr. Fix admits that competition to win the opportunity to coat a given device occurs before any revenue is generated, and that the revenue that is generated can continue for many years or even decades after the competition has occurred:

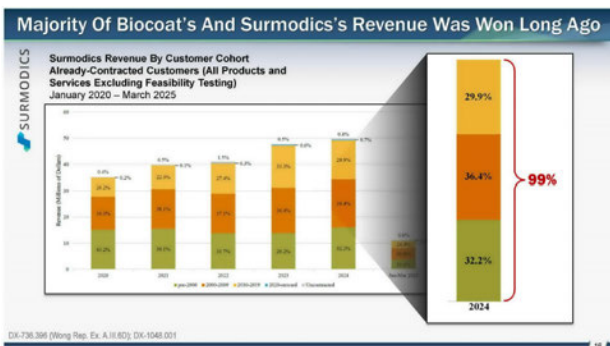
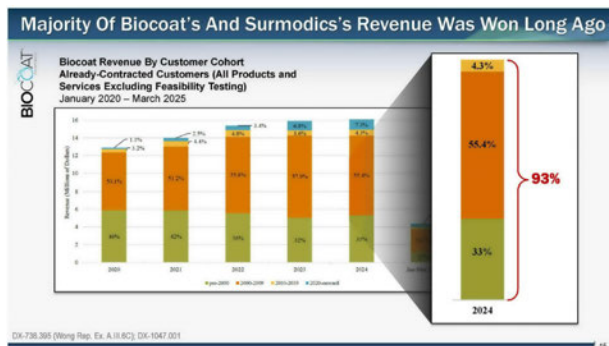
The Court: And just to be clear, ... the revenue numbers you have for these customers ... this would represent Biocoat and Surmodics winning a competition to coat devices regardless of when they won that competition. Whether it's 20 years ago or one year ago, this would represent the revenue –the totality of the revenue that each of these companies received from these particular customers.

The Witness: This represents the totality of the revenue that these suppliers receive from these customers regardless of when the medical device was FDA approved or even regardless of if it was FDA approved because this incorporates a small amount of revenue for, you know, new devices in development.

Tr. 1875:11-1876:16 (Fix); *see also* Tr. 1545:13-21 (Wong).

176. The magnitude of revenue is largely determined by factors unrelated to coating competition, such as the success or failure of the coated medical device itself. Tr. 1555:21-1557:1 (Wong). Dr. Fix's revenue-based shares are thus biased and do not accurately measure a firm's current or future competitive significance. Tr. 1860:15-1861:2 (Fix) (acknowledging that revenues reflect old wins from "customers with which they've had a relationship with for a long time and on devices that have been FDA approved for many years").

177. Dr. Wong analyzed the age of Biocoat's and Surmodics's revenue, finding that 93% of Biocoat's 2024 revenue by customer and 99% of Surmodics's 2024 revenue by project were driven by customers that were first won more than five years ago:



Tr. 1542:18-1546:9 (Wong) (discussing DDX-008.015 and DDX-008.016).

178. Dr. Wong also highlighted certain problems inherent in Dr. Fix's revenue-based shares. As an illustrative example of the overall bias caused by revenue, Dr. Fix included nearly \$4 million in Surmodics's 2024 revenue from [REDACTED] in his market share calculations [REDACTED]

[REDACTED] even though Surmodics did not win any of [REDACTED] newly approved devices in 2024. Tr. 1548:11-17 (Wong) (discussing DDX-008.017 below).

Dr. Fix's Revenues Do Not Comport With Actual Wins			
Dr. Fix's Revenue:	Dr. Fix's Revenue:	Dr. Fix's Revenue:	Dr. Fix's Revenue:
Biocoat:	Surmodics:	Biocoat:	Surmodics:
\$981,733	\$554,782	\$789,061	\$3,819,712
Opportunities:	Opportunities:	Opportunities:	Opportunities:
Total Wins	Total Wins	Total Wins	Total Wins
4 0	4 0	6 0	6 0

DX-736.327, 360-361 (Wong Rep. Ex. 05, 15); DX-1021.001; DX-1032.301; PX0000.008 (Corrected Fix Rep. Fig. 1); PX0001.001 (Corrected Fix Rep. Fig. 1); PX0019.001 (Corrected Fix Rep. Ex. 1)

179. Dr. Fix's criticism of Dr. Wong's analysis—that Biocoat and Surmodics had new opportunities with three of these customers “in the past two or three years”—does not undermine the fact that Dr. Fix's 2024 market share calculation for Biocoat included revenue from customers from whom Biocoat did not win a single opportunity in 2024. Tr. 1547:7-24 (Wong). Dr. Fix's revenue shares do not reflect Biocoat, Surmodics, or any other player competing for and winning new business in 2024. *Id.* Rather, as the Court observed and Dr. Fix confirmed, “the revenue numbers you have for these customers, this would be the totality of the revenues that Biocoat and Surmodics obtained from these customers, whether the contract was entered into 25 years ago or one year ago[.]” Tr. 1875:11-1876:16 (Fix).

180. Furthermore, Dr. Fix’s market share calculations depend on an adjusted U.S.-only market of \$84.5 million, a figure he arrived at by making ad hoc allocations of revenues based on aggregate information about where each customer’s medical devices are sold. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] PX4000-143 (Fix Rep. Ex. 2); *see also* Tr. 228:12-17 (Ankeny) (market is \$150-200 million).

181. There is no solution or adjustment able to remedy the bias caused by legacy coatings when relying upon revenues for market shares. Tr. 1538:17-1540:9 (Wong) (Dr. Fix’s market shares are “so heavily skewed and, frankly, biased by legacy revenue” and “far overstate the competitive significance, particularly of Biocoat and Surmodics”); 1571:10-11 (Wong) (“[T]he calculation’s just so fatally flawed, there’s no adjustment that would give you an accurate picture.”). Nonetheless, Dr. Fix offered two additional analyses—his “new” customer analysis, and his analysis based on what he described as “revenue from precommercialization, feasibility testing and development revenue.” Tr. 1860:22-1861:2 (Fix). As shown below, these too are flawed.

B. Dr. Fix’s Alternative Market Shares Based On “New Customer Revenues” Are Flawed As Well

182. Dr. Fix’s alternative market share calculations based on “new” customer revenue does not measure current competition. Tr. 1566:13-20 (Wong). Dr. Fix identifies “new customer” revenue by isolating revenues from customers that purchased coatings for their commercialized devices in 2023 but not in 2021 or 2022. PX4000.080-.081 (Fix Rep.). Using these figures, Dr. Fix estimates

that Surmodics had 63.1% and Biocoat 13.2% of new customer revenues in 2023. *Id.*

183. These figures suffer the same issues as his 2024 revenue-based market shares. Section V.A.; DX-736.191-.193 (Wong Rep.); Tr. 1567:19-1569:2 (Wong). Notably, most of the “new customers” identified by Dr. Fix actually signed their contracts pre-2020. DX-736.192-.193, n.615 (Wong Rep.); Tr. 1567:19-1568:8 (Wong). Dr. Fix conceded that he “didn’t intend to do an analysis based on contract date,” Tr. 1867:17-18 (Fix), that the customers were not actually “new,” *id.* 1867:23-25, 1868:14-23, and that the analysis would count a customer as a “new customer” even though it had a contract with Surmodics in 2020. *Id.* 1870:7-1871:5. In fact, Dr. Fix conceded in responding to a question from the Court, that his “new customer” analysis was better characterized as a “more recent legacy” analysis. *Id.* 1864:4-1865:4.

184. Further, by focusing on new customers and working with a small and incomplete dataset, Dr. Fix adds variability and randomness to his revenue-based market shares. Out of the 15 outsourced hydrophilic coating providers Dr. Fix includes in his relevant market, he excludes Argon, Coatings2Go, and TUA System, which did not produce sufficiently detailed data in discovery.

Dr. Fix also leaves out four other suppliers because (applying his erroneous definition) they had zero “new” revenues as of 2023, further distorting his results. Tr. 1568:9-1569:2 (Wong); DX-736.192-.193, n.618 (Wong Rep.).

██████████ This reflects the inherent limitations and skewness of trying to use “more recent legacy” coatings revenues from commercialized devices.

185. Even after attempting to account for the Divestiture, Dr. Fix’s “new customer” analysis fails.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. Dr. Fix’s Alternative Market Shares Based On Feasibility Testing Revenue Also Are Unreliable And Biased

186. Dr. Fix put forward one other alternative market share calculation, this one based on revenue from feasibility testing. Tr. 1120:11-1121:1 (Fix). But as Dr. Wong explained, Dr. Fix’s analysis is unreliable. DX-736.193-.195 (Wong Rep.). As one example, the feasibility testing revenue data upon which Dr. Fix relied are far from complete—at least seven suppliers did not produce feasibility testing revenue data, which severely skewed the results. Tr. 1933:6-1934:10 (Fix). In fact, Dr. Fix claims that [REDACTED]

[REDACTED]

[REDACTED] which makes feasibility testing revenue an inherently biased and unreliable method to calculate market shares.

187. In his rebuttal testimony, Dr. Fix advanced a modified version of his feasibility testing revenue analysis that purported to account for the Divestiture, but this adjustment is inaccurate (on top of the fatally flawed market shares) because it merely assigns to Integer Biocoat’s revenue from feasibility testing conducted on its UV coating. Tr. 1862:2-21 (Fix). Dr. Fix does not even attempt to account for the Divestiture of Biocoat’s currently marketed thermal coatings to Integer. *Id.* 1122:21-1124:11 (Dr. Fix’s adjustment for the Divestiture is based on the mistaken belief that “what’s being divested is ... Biocoat’s UV-cured product” and his unsupported assumption that

“Biocoat has more things that they can try with the customer’s device ... than Integer would have.”). Nor does this adjustment account for Integer’s revenue from the feasibility testing that it already does today. *Id.* 1934:11-22 (Q: “But the Integer slice that you have put on this graph for your feasibility testing, that does not include any of Integer’s revenue from the feasibility testing that it does today, correct? A. That’s correct.”).

D. None Of Dr. Fix’s Market Shares Reliably Account For The Divestiture

188. In the end, any attempt by Dr. Fix to revise any of his market shares to account for the Divestiture falls short. As detailed above, Dr. Fix’s revenue-based shares are fundamentally flawed by the inclusion of legacy revenue, and this problem cannot be overcome by his attempts to calculate shares based on so-called “new” customers or feasibility testing. Sections V.A-C. Any attempt to account for the Divestiture using any these shares suffers from a garbage-in-garbage-out problem.

189. The second fundamental problem is that Dr. Fix bases his divestiture adjustments on his understanding that “Integer won’t have that capability [to compete] right away” and will be “a smaller player, smaller than some other players in this market.” Tr. 1862:22-1863:24 (Fix). In other words, Dr. Fix credits Integer with only the small amount of UV revenue that Biocoat has today and fails to account for any growth. *Id.* 1862:5-21, 1865:18-1866:4. This approach underscores the fundamental flaw in his analysis in not looking to the go-forward competitive significance of the firms. But as Dr. Fix acknowledges, and as Mr. Senn confirmed, Integer “certainly” intends to grow. Tr. 1862:22-1863:24 (Fix); 1732:23-1733:9 (Senn); *see also* Section II.C.

E. Properly Calculated Market Shares Raise No Competitive Concern

190. Rather than measure market shares based on legacy revenue, a far more accurate and probative metric is based on each supplier’s count of sales opportunities won recently. DX.736.185-.188 (Wong Rep.). As Dr. Fix himself states, “coating suppliers typically focus on winning business for new devices in development or new generations of existing devices.” PX4000-022-023, -027-

028 (Fix Rep.). An opportunity is not fully “won” until a medical device completes FDA approval, as after that point customers are “locked in” and rarely, if ever, switch coatings. Section II.F. In contrast to Dr. Fix’s revenue-based market shares, Dr. Wong offers shares based on public FDA data of approved devices reflecting new opportunities at “the point where that ... win or selection is cemented.” Tr. 1554:10-14 (Wong).

191. Specifically, Dr. Wong analyzed FDA records of approved medical devices in the U.S. likely to use hydrophilic coatings as of 2024. Tr. 1551:17-1553:16 (Wong). Based on the FDA records, Dr. Wong identified 213 medical devices approved in 2024 that are catheters, guidewires, introducers, other neurovascular, cardiovascular, or interventional devices that would likely require lubricious coatings. *Id.*; DX-736.188-.190 (Wong Rep.). Public records and records produced in the case confirmed that 91 of the 213 devices had a hydrophilic coating. Tr. 1551:17-1553:16 (Wong). And 45 of the devices were confirmed to use a hydrophobic coating or no coating. Tr. 1551:17-1553:16 (Wong). So, for the 136 devices for which a coating is identified, 67% (91 of 136) used hydrophilic coatings.

192. For the remaining 77 coating-eligible devices, and extrapolating from the available data, Dr. Wong estimated that 67% (*i.e.*, 52 of 77) devices had a hydrophilic coating (which is conservative, given a likely higher percentage of these types of devices require hydrophilic coatings). Tr. 1551:17-1553:16, 1602:22-1603:22, 1607:3-9 (Wong). In total, Dr. Wong estimated that 143 (91 confirmed and 52 estimated) devices of the 213 coating-eligible devices had a hydrophilic coating. Tr. 1551:17-1553:16 (Wong). In essence, the 143 hydrophilic coating-eligible devices approved by the FDA in 2024 conservatively represent the universe of potential “U.S. sales opportunities” that hydrophilic coating providers may compete for in a given year when applying Plaintiffs’ own relevant market

definition. DX-736.185-.188 (Wong Rep.). Dr. Wong then calculated what share of these U.S. sales opportunities Biocoat and Surmodics coated and “won” in 2024. *Id.* .188-.190.

193. Using the shares derived from public FDA data, Dr. Wong finds that the parties have “very modest” market shares: the highest market share estimated *without* the Divestiture is no more than about 27%, and an HHI of no more than about 1500. Tr. 1558:24-1561:18 (Wong).

194. Dr. Wong also conducted alternative market share estimates based on variations in the putative market, such as including all coating-eligible devices (*i.e.*, all sales opportunities that chose either hydrophilic or non-hydrophilic lubricity), and he determined that in all scenarios the parties’ combined shares would be below 30%. Tr. 1560:21-1561:18 (Wong). Dr. Wong also estimated market shares *inclusive* of the Divestiture, and determines the parties’ combined shares are no more than about 24%. *Id.* 1561:19-22.

195. Plaintiffs’ and Dr. Fix’s criticisms of Dr. Wong’s opportunity-based shares are meritless. First, Dr. Fix argues that his revenue-based market shares are more informative, but he also concedes that “the annual revenues earned by hydrophilic coating suppliers today are influenced by competition that occurred years ago.” PX4000-075 (Fix Rep.). Dr. Fix argues that Dr. Wong’s assumption about the 77 devices with unknown coating information inflates the denominator. But as Dr. Fix recognizes, even if only 16 of those 77 devices have a hydrophilic coating, the parties’ combined market share would be less than 30%. Tr. 1915:20-1916:16 (Fix). Although he originally claimed that “all or almost all” of the 77 devices were not coated, *id.* 1900:20–25, Dr. Fix agrees that further research has confirmed that at least some of these 77 devices have a hydrophilic coating, including two that he identified himself. *Id.* 1917:13-17, 1918:17-1919:5, 1921:25-1922:10.

196. Dr. Fix further argues that Dr. Wong’s assigning equal weight to each device ignores differences in device volume, customer size, and revenue, which he alleges does not reflect the

economic significance of each opportunity. [REDACTED] Tr. 1130:15-1131:12 (Fix). But as Dr. Wong explained, it is appropriate to assign equal weight to each opportunity, because at the time of competition, the coating supplier could not predict (let alone competitively dictate) how successful the device will be—and thus how much revenue the coating supplier will earn. Tr. 1615:24-1616:14, 1619:24-1620:11 (Wong).

197. Dr. Fix argues that the FDA-approved devices do not reflect all sales opportunities because coating providers could compete for coating opportunities on already commercialized devices, but Dr. Fix cannot point to a *single* instance where a customer switched coatings on a device in production. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

198. More generally, even when Dr. Fix calculated shares from the FDA opportunity data based on the unrealistically conservative assumption that only 88 (rather than 143) of the 213 devices have hydrophilic coatings, his estimated shares ranged from 35.2% to 44.3% for the parties combined, which is a vast change from his estimated share of 60.4% based on his “preferred” method of using revenues. PX4013-071 (Fix Rebuttal Rep.). The stark contrast between share estimates when moving from revenue- to opportunity-based shares further highlights the bias and unreliability inherent in Dr. Fix’s revenue-based shares.

VI. THE MODIFIED TRANSACTION IS NOT LIKELY TO LEAD TO A SUBSTANTIAL REDUCTION OF COMPETITION IN ANY RELEVANT MARKET

A. Plaintiffs' Market Shares Inaccurately Predict The Modified Transaction's Probable Effect On Competition

199. As previously discussed, market shares based on revenue do not reflect current or future competitive dynamics. Section V.A.

B. The Divestiture Eliminates Any Possibility Of Anticompetitive Effects

200. The merged firm will continue to compete against Integer in sales of UV and thermal coatings, and Integer will add a net new competitor offering thermal coatings. Section III.B.

C. Plaintiffs Fail To Demonstrate That There Is Currently Meaningful And Frequent "Head-to-Head" Competition Between Biocoat And Surmodics

201. Plaintiffs have not shown that Biocoat and Surmodics engage in "head-to-head" competition in a way that meaningfully impacts price or quality for outsourced hydrophilic coatings.

202. Instances of head-to-head competition between Biocoat and Surmodics are infrequent. Tr. 1582:16-1583:1, [REDACTED] (Wong) ("Biocoat and Surmodics do not interact competitively frequently; and, even when they do, there is a substantial amount of competition."); [REDACTED]

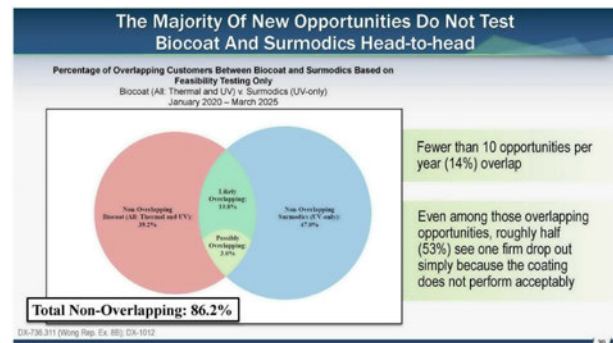
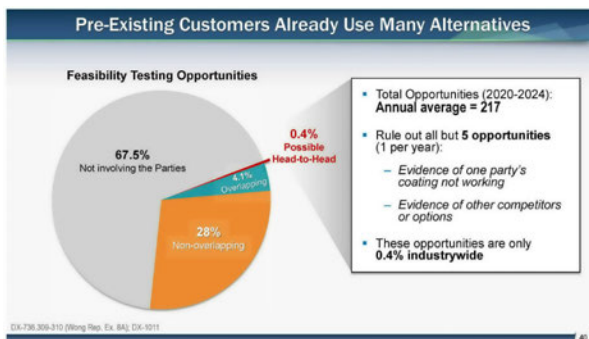
[REDACTED] DX-414.001 (de Freitas stating in 2023, "Although we are not going up against Surmodics directly very often, it is much more typical that we are competing with Harland."); [REDACTED]

203. According to Dr. Wong's analysis, of the 104 existing customers of either Biocoat or Surmodics, only 15 have used both companies in the last five years, meaning that more than 85% of the parties' current customers do not treat the two companies as substitutes, and that number would

likely be much larger if customers who do not currently use Biocoat or Surmodics are included. Tr. 1584:19-1585:15 (Wong) (discussing DX-736.286-.287 (Wong Rep. Ex. 3A-B)). And where there is overlap between Biocoat and Surmodics, there also is competition from other suppliers, [REDACTED]

[REDACTED] Tr. 1585:16-1586:12 (Wong) (discussing DX-736.331 (Wong Rep. Ex. 11A) and testifying that “even if we’re limited to just the few customers that use both parties, there’s a significant amount of competition for those customers”).

204. Dr. Wong’s analysis also shows that, when looking at Biocoat’s and Surmodics’s 370 combined prospective new sales opportunities from January 2020 to March 2025, both were feasibility tested “head-to-head” in fewer than 10 opportunities a year (less than 14% of the parties’ sales opportunities), and even among those overlapping opportunities, roughly half (53%) see one firm drop out due to issues with coating performance:



DDX-008.039; *see also* Tr. 1586:13-1588:14 (Wong) (discussing Exs. 8A-B, 8I of his report, DX-736.303.111-.112, .309-.311, .324) (“[T]here were 51 new opportunities in the last five years that overlapped. That’s only about ten a year. A little over half of those, one of the two companies’ coatings just didn’t work. The company dropped out for reasons unrelated to competition. And, again, often the coating just doesn’t work, even where you expect it might.”).

205. To further contextualize the relative infrequency of overlap, Dr. Wong calculated that there were, on average, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Further, Dr. Wong shows that for all but five of the overlapping opportunities (*i.e.*, one per year), there is evidence that either Biocoat's or Surmodics's coating did not work or that there were other competitors or options for the same opportunity. DX-736.111-.112 (Wong Rep.); Tr. 1586:13-1588:14 (Wong) (discussing DDX-008.040); Tr. 1935:24-1937:18 (Fix). Together, that implies that only a tiny fraction (specifically, 0.4%) of industry-wide feasibility testing opportunities involved Biocoat and Surmodics as possibly "head-to-head" competitors. DX-736.025, .112 (Wong Rep.); Tr. 1587:20-1588:14 (Wong). Dr. Fix did not provide a response to this analysis, conceding that he did not "recall this analysis in sufficient detail" and "would have to look a lot more closely" at Dr. Wong's report. Tr 1935:24-1938:22 (Fix).

206. Notwithstanding the overall lack of frequent "head-to-head" competition between Biocoat and Surmodics, Plaintiffs attempt to manufacture anecdotal examples of such competition. As even Dr. Fix admitted, the handful of customers who testified are not representative of the market as a whole. Tr. 1261:25-1262:20 (Fix). Thus, almost all of Plaintiffs' examples are opportunities that include several other coating suppliers and/or are occasions when Biocoat's or Surmodics's coating did not work, meaning that their coating was not a viable option. For example:

207. [REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

208. **Contego**. While Mr. Stern testified that both Biocoat and Surmodics were “competing” for Contego’s business, Contego also considered coatings from TUA and Hydromer, and thus had other options. Tr. 973:11-17 (Stern). Mr. Stern also testified that Biocoat was selected for performance reasons, as “the engineers who did the evaluation felt that [Biocoat] had the best results” in terms of “lubric[ity], uniformity, and adherence.” *Id.* 992:8-17.

209. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

210. **Scientia**. [REDACTED]

[REDACTED]

[REDACTED]

And while Scientia tested ISurTec and Biocoat for the BFG, neither supplier’s coating worked; Surmodics’s coating was the only coating that ever worked for the device. *Id.* 487:5-489:2.

211. Maduro. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

212. Stryker. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

213. Alembic. While Alembic tested both Surmodics and Biocoat in a “parallel process” for its APRO catheters, after more than a year of testing, Surmodics’s coating continued to generate high particulate levels, presenting a safety issue that Surmodics was never able to resolve. Welsh Dep. 40:9-41:12. Surmodics’s coating was thus not a viable option for Alembic. *Id.* 77:19-21.

214. [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

D. Price Is Rarely A Consideration When Choosing A Coating Supplier

215. While Plaintiffs argue that Biocoat and Surmodics “compete on price,” there is no evidence that any “head-to-head” competition resulted in lower pricing for any customer for a commercialized medical device. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Moreover, even if Plaintiffs had established price competition at the feasibility stage (they did not), coating selection is based on performance, and if a coating does not pass feasibility testing, it is not a viable option. Section II.D.

E. Plaintiffs Did Not Put Forward Any Evidence Of Actual Consumer Harm From The Original Or Modified Transaction

216. While Plaintiffs have made allegations of consumer harm arising from supposed price increases and potential loss of innovation, their theories are unsupported by any evidence.

217. There is no evidence that, after the Modified Transaction (or even the Original Transaction), customers will face higher prices for hydrophilic coatings. [REDACTED]

[REDACTED] And the evidence shows that customers pick a coating supplier based on performance, not price, and do not play coating suppliers off of one another to obtain better pricing. Section II.D.

218. Nor is there evidence that GTCR has played any role in Biocoat's pricing, or that GTCR intends to (or could) increase the merged firm's prices if the transaction is consummated. Tr. 584:1-14 (de Freitas) ("Q. Either before, during, or after the acquisition of GTCR of Biocoat, did GTCR ever have a role in changing expedited pricing fees? A. No."); 809:12-13 (Moran) (Q. Did [GTCR] ask you to increase prices? A. No, they did not."); Nair Dep. 122:9-11 ("Q. Did GTCR model price increases when evaluating the acquisition of Surmodics? A. No."). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

219. Customers, including Plaintiffs' witnesses, are not concerned about the Original Transaction or the Modified Transaction. [REDACTED]

[REDACTED] Brenizer Dep. 73:2-7 (Teleflex has no opinion regarding the transaction); Dang Dep. 97:10-98:3 (Terumo Neuro is "agnostic" to transaction); Hatcher Dep. 47:10-48:8, 56:11-57:2 (no concerns about proposed transaction); H. Patel Dep. 92:3-5 (no concerns about the transaction); Hiatt Dep. 120:20-23 (Cook does not have any concerns regarding the transaction); Rentschler Dep. 15:22-16:1 ("Q. ... Do you have an opinion on the proposed transaction between Biocoat and Surmodics? A. I don't."); Jalgaonkar Dep. 121:14-121:17 (same for Balt).

220. There also is no evidence that innovation will cease because of the proposed transaction. Witnesses from Integer, the merged firm, and even competitors testified that they intend to continue to innovate—and that they will need to in order to win business going forward. Tr. 1733:10-1734:4 (Senn) ("Our customers come to us to help them develop new products. And we intend to be viewed as an innovator within the market, so that we can work with them to bring these new products to market."); 1453:5-16, [REDACTED]

[REDACTED] 1349:15-1350:5 (Hance) (Integer has "the financial wherewithal and the intent to invest in the future" and will bring

“competitive intensity”); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The Modified Transaction will not change—and given Integer’s plans, will in fact enhance—that reality. Sections III.B-C.

221. While Plaintiffs repeatedly suggested that if the transaction closes, patient safety will somehow be jeopardized, *see, e.g.*, Tr. 13:9-12, 16:13-16, 1976:7-11, there is no evidence to support their hyperbole. The FDA, of course, will continue to regulate and oversee the safety of medical devices in the U.S. even after this transaction is consummated. Tr. 1095:25-1096:15 (Fix); McCormack Dep. 101:12-102:22.

F. Dr. Fix’s “Merger Simulation” Is Irrelevant Because It Does Not Align With Competitive Realities Or Account For The Divestiture

222. Dr. Fix testified that based on his merger simulation model, the removal of the competitive constraint by one of Surmodics and Biocoat would give the other party an incentive to increase price. Tr. 1143:8-15 (Fix). But Dr. Fix admitted that his numbers are just that: a modeled simulation. *Id.* 1143:16-1144:1 (“I’m not saying definitely, and price increases greater or less than this on average are possible. I also think different customers would be affected differently[.]”).

223. Dr. Fix also did not attempt to quantify any individual customer’s preferences or calculate the impact of the merger on any customer, despite his admission that customer preference may be device-specific. ¶ 44; *see also* [REDACTED]

224. Dr. Fix’s merger simulation also fails to operate within the competitive realities of the industry. Dr. Fix admits that his merger simulation model [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In other words, the model assumes that Surmodics and Biocoat are most likely to be customers' preferred options for a new opportunity—and the assumption is based solely on the relative size of Surmodics's and Biocoat's revenues, the vast majority of which flow from legacy opportunities won five or more years ago. *Id.*; Sections II.H, V.A. Dr. Fix's model is therefore inconsistent with commercial realities, unreliable, and uninformative.

225. Even setting aside issues of reliability, Dr. Fix conceded that his merger simulation does not account for the Divestiture to Integer. Tr. 1144:16-1145:3, 1145:14-1146:15 (Fix). For this reason alone, Dr. Fix's merger simulation is not probative of the competitive effects of the actual transaction, as his estimated price effects take place in a world in which Integer does not exist as a competitor; it follows, as Dr. Wong explains, that "Dr. Fix's analysis is premised on a world that will not occur." DX-736.120 (Wong Rep.).

VII. CREDIBILITY FINDINGS

226. Plaintiffs' expert, Dr. Fix, did not conduct a credible or reliable analysis of the market he was tasked with examining. Apart from his flawed, revenue-based market share calculations (Section V), Dr. Fix's analysis was not based on any data and did not use any recognized methodology. Dr. Fix did not conduct any systematic analysis of key questions relating to Plaintiffs' market definition, including what portion of customers or applications are UV-only or thermal-only; what portion of customers or applications can use hydrophobic or no coating options; or what portion of customers or applications can use in-house coating options. Section IV.C. [REDACTED]

[REDACTED]; Section IV.C.

227. The evidence that Dr. Fix relies upon includes testimony of dubious reliability, such as a figure about the substitutability of UV and thermal coatings from a witness who had no personal

knowledge of the figure, but obtained the information from a colleague who in turn obtained it from a 10-year-old market study on which the company does not rely anymore. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Additionally, when critiquing Dr. Wong's FDA-based market share calculations, Dr. Fix went from assuring the Court that "the best assumption about those 77 is that they don't have a hydrophilic coating and they don't have a hydrophobic coating ... I believe that to be true in all or almost all of those cases" (*id.* 1900:17-25), to, less than ten minutes later, admitting that further research had confirmed that at least some of these 77 devices have a hydrophilic coating, including two that he identified himself. *Id.* 1915:4-19, 1917:13-19, 1918:17-1919:5, 1921:25-1922:10.

228. By contrast, Defendants' expert, Dr. Wong, conducted a rigorous, data-driven analysis supported by robust cross-checks. He evaluated Dr. Fix's market definition, including by distinguishing conglomerate business units to avoid overstating dual-method customers (Tr. 1579:4-1580:1 (Wong)), conducting competitive effects analysis that shows little substitutability between UV and thermal (DX-736.160-.161 (Wong Rep.)), and providing concrete examples that highlighted customer variability (Tr. 1573:2-1577:11 (Wong)). Dr. Wong analyzed publicly available FDA approval data—the federal government's own dataset—to count actual U.S. sales opportunities won in 2024, calculated market shares and HHIs under 16 different scenarios, and consistently found combined shares below 30% and HHIs below 1,800, even under conservative assumptions. Tr. 1553:17-1554:2, 1560:21-1561:22 (Wong); DX-736.185-.190 (Wong Rep.); Section V.E. Dr. Wong was forthright in correcting minor outliers in his FDA dataset (such as five "computer cable" or similar entries), reran his calculations to confirm that these changes had a negligible effect, and

tested Dr. Fix's proposed exclusions (two in-house devices) to demonstrate that they did not alter his conclusions. Tr. 1562:13-1564:3 (Wong).

229. Dr. Wong's overlap analysis was equally thorough: he conducted analyses using both commercialized customer counts and feasibility testing opportunities, showing that head-to-head competition between Biocoat and Surmodics is infrequent and that customers routinely consider and use multiple alternative suppliers. Tr. 1584:13-1588:14 (Wong). Taken together, Dr. Wong's transparent methodology, careful attention to data integrity, and willingness to test alternative scenarios underscore the reliability of his expert analysis.

VIII. THE EQUITIES WEIGH AGAINST AN INJUNCTION

230. Granting Plaintiffs' request for a preliminary injunction until the conclusion of the FTC's administrative proceeding will have the inevitable effect of blocking the transaction permanently.

231. The termination date in the merger agreement is [REDACTED]

The administrative proceeding is set to commence on December 1, 2025. Order, *GTCR BC Holdings, LLC*, No. 9440 (F.T.C. June 10, 2025). As a result, if the Court grants the preliminary injunction, it will effectively kill the transaction and the administrative proceeding almost certainly will not take place. Dkt. 207-1 at 10 (“[I]n the event the Court grants the FTC's motion, Defendants will not have sufficient time to complete the Part 3 administrative hearing before the agreed-upon expiration date for the Proposed Acquisition ...”).

232. Plaintiffs present a moving target with respect to the public interest they allege justifies a preliminary injunction. Prior to the hearing, Plaintiffs claimed that “the loss of substantial head-to-head competition between Biocoat and Surmodics will be difficult, if not impossible, to reverse should Defendants consummate the Proposed Acquisition before a full merits hearing can take place.” Dkt. 173 at 53. Apparently recognizing the weakness of that argument—there is little head-to-head competition between Biocoat and Surmodics (Section VI.C)—Plaintiffs now claim that the

harm to the public interest is that “proprietary information would be shared between merged companies in a way that cannot be unscrambled.” Tr. 1974:7-12 (Pls. Closing). Plaintiffs, however, provided no evidence to support either of these claims.

233. In stark contrast to Plaintiffs’ speculation, the public would benefit from the transaction. First and foremost, the Divestiture will *increase* the number of suppliers of thermal-cured coatings, while keeping the number of UV-cured coating suppliers the same. Section III.B. Further, “the combination of the companies’ different personnel and expertise has the potential to benefit—not harm—innovation,” and “the combination of the companies’ operations has the potential to standardize and streamline the supply chain for manufacturers.” DX-736.134 (Wong Rep.); *see also* Tr. 1318:21-1324:24 (Hance) (discussing transaction benefits reflected in DDX-002, including that (1) utilizing both Surmodics and Biocoat manufacturing facilities will “[r]educ[e] costs,” provide “faster delivery times,” “put our production close to the customer,” and provide “supply chain resiliency”; (2) utilizing Biocoat’s “cost improvement program” at Surmodics facilities will “lower the cost of production”; (3) there are cost benefits from taking Surmodics private; and (4) the companies’ knowledge sharing including Surmodics’s “lyophilization technology” and Biocoat’s “exceptionally good automation ... promises some significant benefits as well”); [REDACTED]

[REDACTED]

[REDACTED]

234. Integer already has a go-to-market plan and has begun investing in its facilities so that it can compete as soon as the transaction closes. Section III.C.

235. And both Integer and the merged entity have the intention and ability to innovate post-transaction for the benefit of customers. Tr. 1452:13-19 (Hergenrother); 1650:7-11, 1651:9-11 (Wong); 1733:15-1734:4 (Senn); 569:7-15 (de Freitas); 881:5-6 (Marker); DX-107.009 (Divestiture

[r]einforces Integer’s commitment to delivering ... innovation for current and future customers.”).

CONCLUSIONS OF LAW

236. Plaintiffs fail to show that they are entitled to a preliminary injunction to block the proposed merger of BC Holdings and Surmodics. Plaintiffs also fail to show that GTCR LLC is a proper party to this litigation.² Nonetheless, to avoid an unnecessary dispute and because it cannot consummate the proposed transaction regardless, GTCR LLC agrees to be bound to the same extent as BC Holdings by any preliminary injunction issued by this Court that would prevent BC Holdings from acquiring Surmodics, pending the adjudication of an administrative complaint issued by the FTC.

IX. LEGAL STANDARDS

A. The Preliminary Injunction Standard: Section 13(b) Of The FTC Act

237. A preliminary injunction “is an extraordinary equitable remedy that is never awarded as of right.” *Starbucks Corp. v. McKinney*, 144 S. Ct. 1570, 1576 (2024). This is particularly so in the merger challenge context under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), where the preliminary injunction proceeding “almost always obviates the need” for further administrative proceedings before the FTC, meaning the district court’s decision for all practical purposes determines whether the transaction will close. *In the Matter of Tempur Sealy Int’l, Inc.*, 2024 WL 4544179, at *1 (F.T.C. Oct. 15, 2024); *see also FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1084-85 (N.D. Cal. 2023) (“the issuance of a preliminary injunction blocking an acquisition or merger may prevent the transaction from ever being consummated”). This is true here. ¶¶ 230-31.

² Because GTCR LLC is not a party to the Merger Agreement, did not file the HSR Notification (¶ 76), and is not the “ultimate parent entity” to either merging party, GTCR LLC cannot consummate the Original Transaction. *See* 15 U.S.C. § 18a(a); 16 C.F.R. § 801.1(a)(1). And because an injunction against GTCR LLC will do nothing to redress the alleged future harm of the consummated transaction, (1) Plaintiffs lack Article III standing to sue GTCR LLC, *see LSP Transmission Holdings II LLC v. Huston*, 131 F.4th 566, 577-76 (7th Cir. 2025); and (2) GTCR LLC is not “about to” violate any antitrust laws within the meaning of Section 13(b), 15 U.S.C. § 53(b).

238. Plaintiffs argue that to obtain a preliminary injunction under Section 13(b), they need only “raise substantial doubts about the transaction.” Dkt. 173 at 10-11 (quoting *FTC v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1074 (N.D. Ill. 2012)). Following *Starbucks*, however, to obtain a preliminary injunction under Section 13(b), Plaintiffs must (1) make a “clear showing” of a likelihood of success on the merits, and (2) demonstrate that the public interest and equities favor an injunction. *Starbucks*, 144 S. Ct. at 1575-77; *see also FTC v. Tempur Sealy Int’l, Inc.*, 768 F. Supp. 3d 787, 814 (S.D. Tex. 2025) (applying *Starbucks* to a Section 13(b) case brought by the FTC); 15 U.S.C. § 53(b) (removing irreparable injury requirement).

239. “Given the stakes, the FTC’s burden is not insubstantial.” *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004). “A showing of a fair or tenable chance of success on the merits will not suffice for injunctive relief.” *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999). Instead, Plaintiffs “must show that there is a ‘reasonable probability’ or ‘appreciable danger’ that the acquisition may substantially lessen competition,” not merely a possibility. *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 290 (D.D.C. 2020); *see also United States v. Citizens & S. Nat’l Bank*, 422 U.S. 86, 122 (1975) (“The Clayton Act is concerned with ‘probable’ effects on competition, not with ‘ephemeral possibilities.’”) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)); *FTC v. Meta Platforms, Inc.*, 654 F. Supp. 3d 892, 911 (N.D. Cal. 2023) (FTC is “required to provide more than mere questions or speculations supporting its likelihood of success on the merits”). “Antitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future.” *Arch Coal*, 329 F. Supp. 2d at 116-17.

240. The Seventh Circuit has made clear that “[l]ikelihood of success on the merits” is not limited to the FTC’s likelihood of success in its own internal administrative proceeding, but rather “a full

administrative proceeding before the FTC, followed by judicial review ... in one of the courts of appeals.” *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 903 (7th Cir. 1989).

B. The Substantive Law: Section 7 Of The Clayton Act And The *Baker-Hughes* Burden Shifting Framework

241. Section 7 of the Clayton Act requires Plaintiffs to prove that the effect of the Modified Transaction will be “substantially to lessen competition” in a “line of commerce”—that is, in a relevant antitrust market. 15 U.S.C. § 18; *see Int’l Shoe Co. v. FTC*, 280 U.S. 291, 298 (1930) (“some lessening of competition[] is not forbidden”). “[P]laintiffs have the burden on every element of their Section 7 challenge, and a failure of proof in any respect will mean the transaction should not be enjoined.” *Arch Coal*, 329 F. Supp. 2d at 116.

242. Courts apply a burden-shifting framework to analyze the legality of a horizontal merger under Section 7. First, Plaintiffs must establish a *prima facie* case that the transaction “will substantially lessen competition” by showing that it “will lead to undue concentration in the market for a particular product in a particular geographic area.” *United States v. Baker Hughes Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990). If Plaintiffs do not prove their *prima facie* case, they cannot obtain a preliminary injunction. *See Tenet Health*, 186 F.3d at 1051; *RAG-Stiftung*, 436 F. Supp. 3d at 287.

243. If Plaintiffs establish their *prima facie* case, Defendants bear the burden to show that the “*prima facie* case inaccurately predicts the relevant transaction’s probable effect on future competition.” *Baker Hughes*, 908 F.2d at 982, 991. A “clear showing” is not required, as imposing such a standard on Defendants “in effect shifts the government’s ultimate burden of persuasion to the defendant.” *Id.* at 983, 989.

244. If Defendants carry their burden, “the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.” *Id.* at 983; *see also* Fed. R. Evid. 301.

C. The Relevant Transaction Includes The Divestiture

245. In applying Section 7, “the relevant transaction ... is the proposed acquisition agreement *including* the proposed divestiture.” *United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 134 n.5 (D.D.C. 2022); *see also FTC v. Libbey, Inc.*, 211 F. Supp. 2d 34, 46 (D.D.C. 2002) (amended agreement “becomes the new agreement that the Court must evaluate in deciding whether an injunction should be issued”).³ This means that, under Step 1 of *Baker-Hughes*, Plaintiffs must show that the transaction—inclusive of the Divestiture—is *prima facie* problematic. *UnitedHealth*, 630 F. Supp. 3d at 133 (“[T]he burden of proof regarding the acquisition—including the divestiture—remains on the Government at the *prima facie* stage.”); *FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1093 (N.D. Cal. 2023) (as part of its “*prima facie* burden ... the FTC must address the circumstances surrounding the merger as they actually exist”). Holding otherwise would “allow[] the government to meet its *prima facie* burden based on a fictional transaction.” *UnitedHealth*, 630 F. Supp. at 134 n.5; *FTC v. Arch Coal, Inc.*, 2004 WL 7389952, at *1 (D.D.C. July 7, 2004) (ignoring divestiture would require assessing a “purely hypothetical transaction of the Commission’s making—that none of the parties are proposing”).

246. Plaintiffs’ suggestions that the burden-shifting framework changes, or Defendants’ burden is heightened, because Defendants entered into the Divestiture after Plaintiffs filed their complaint, *see* Tr. 2018:8-18 (Pls. Closing), have no legal support. *See UnitedHealth*, 630 F. Supp. 3d at 128 (divestiture agreement, firewall policy, and customer commitments entered into after filing of complaint). It also would run contrary to the principle that “the law generally favors the

³ As discussed below, evaluating the Divestiture as part of Defendants’ rebuttal burden in Step 2 does not change the end result.

encouragement of settlements.” *Astellas US Holding, Inc. v. Fed. Ins. Co.*, 66 F.4th 1055, 1065 (7th Cir. 2023).

X. STEP 1: PLAINTIFFS FAIL TO SHOW THAT THEY ARE LIKELY TO SUCCEED IN PROVING THAT THE MODIFIED TRANSACTION WILL RESULT IN UNDUE CONCENTRATION IN ANY RELEVANT MARKET

247. To establish their *prima facie* case and benefit from a presumption that the transaction will substantially lessen competition, Plaintiffs must show (i) a relevant market, and (ii) the transaction will lead to undue concentration in that market. *Baker Hughes*, 908 F.2d at 982-83.

A. Plaintiffs Are Not Likely To Establish That “Outsourced Hydrophilic Coatings” Is A Relevant Market

248. The purpose of market definition is to determine “the area of effective competition” and the area of likely harm. *Ohio v. Am. Express Co.*, 585 U.S. 529, 543 (2018) (citation omitted); *see also Tenet Health*, 186 F.3d at 1051 (“Without a well-defined relevant market, a merger’s effect on competition cannot be evaluated,” and the FTC must “identify a credible relevant market before a preliminary injunction may properly issue.”); *United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001) (noting that the “proper definition of the relevant product market” is “key to the ultimate resolution ... since the scope of the market will necessarily impact any analysis of the anticompetitive effects of the transaction”). A properly identified relevant market must “correspond to the commercial realities of the industry.” *Brown Shoe*, 370 U.S. at 336-37.

249. A relevant market has two components: a product market and a geographic market. *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 618 (1974) (“Determination of the relevant product and geographic markets is ‘a necessary predicate’ to deciding whether a merger contravenes the Clayton Act.”) (citation omitted). The parties do not dispute that the appropriate geographic market is the United States. Plaintiffs have not, however, carried their *prima facie* burden to demonstrate their proposed “outsourced hydrophilic coatings for medical devices” market.

250. Market definition analysis “begins by examining the most narrowly-defined product or group of products sold by the merging firms.” *Arch Coal*, 329 F. Supp. 2d at 120. “[T]he clearest indication that products should be included in the same market is if they are actually used by consumers in a readily interchangeable manner.” *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1330 (7th Cir. 1981). The product market “must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn.” *RAG-Stiftung*, 436 F. Supp. 3d at 292 (quoting *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953)); see also *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 26 (D.D.C. 2015) (“market definition is guided by the ‘narrowest market’ principle”); *United States v. H & R Block, Inc.*, 833 F. Supp. 2d 36, 59 (D.D.C. 2011) (discussing “principle that the relevant product market should ordinarily be defined as the smallest product market that will satisfy the hypothetical monopolist test”). While courts occasionally select broader markets when the parties compete to a high degree with different types of products, see *United States v. Continental Can*, 378 U.S. 441, 449-50 (1964), the ultimate question for market definition is the level of substitution between products. See *FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1241 (8th Cir. 2011).

251. Plaintiffs here did not define the market narrowly; instead, they gerrymandered it to capture Defendants’ sales, but nothing more or less. Neither the law nor the facts support Plaintiffs’ proposed definition. Plaintiffs rely on a sample of customers to define which coatings are reasonably interchangeable but have not shown these customers are representative. See ¶ 206 (Dr. Fix testifying that he does not have an opinion that the testifying customers were representative). Rather, the evidence consistently showed that customer choices are device-specific and “depend[] on a host of factors,” preventing “generalizations.” *Sungard*, 172 F. Supp. 2d at 189; see *United States v. Engelhard Corp.*, 126 F.3d 1302, 1306 (11th Cir. 1997) (government failed to establish relevant

market when it did not consider product's "different end-use applications" or establish that customers it interviewed were "representative of the market," especially because product was "designed to achieve very particular end-use requirements"); *see also* Sections II.A, II.D-E.

252. Courts apply two methods to assess whether a plaintiff's proposed market is a distinct relevant antitrust market: (1) the *Brown Shoe* practical indicia; and (2) the hypothetical monopolist test ("HMT"). *FTC v. IQVIA Holdings Inc.*, 710 F. Supp. 3d 329, 354, 368 (S.D.N.Y. 2024); *see also United States v. U.S. Sugar Corp.*, 73 F.4th 197, 206 (3d Cir. 2023).

253. Plaintiffs try to define a market for "outsourced hydrophilic coatings" through application of the *Brown Shoe* factors and purport to confirm it through Dr. Fix's application of an HMT. There are three incurable flaws with Plaintiffs' putative market.

254. *First*, Plaintiffs include UV and thermal options, violating the narrowest market principle. Dr. Fix testified that a market of **just UV-cured coatings** also passed his HMT. *See* Section IV.D. Inclusion of both UV and thermal for devices that unquestionably cannot use one or the other is improper. *See* Sections II.A, II.D.

255. *Second* and *third*, Plaintiffs' market excludes **hydrophobic coatings**, which customers regularly turn to as substitutes, Sections II.A, II.D, as well as **in-house coatings**, to which customers also regularly turn, Section II.C.

256. Plaintiffs' proposed relevant market thus fails to account for the "extremely heterogenous group of customers" who design and manufacture medical devices requiring lubricity and "striking heterogeneity" of those devices' needs. *Sungard*, 172 F. Supp. 2d at 182-83 (finding "government has not met its burden of establishing" a limited product market). Excluding both hydrophobic coatings (for devices that could use them) and in-house coatings (for customers with such capabilities) ignores commercial realities by failing to acknowledge options customers "actually

use[] ... in a readily interchangeable manner.” *Kaiser Aluminum*, 652 F.2d at 1330; *see FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87-89 (N.D. Ill. 1981) (rejecting FTC’s narrow market, which did not account for “competition at the end use level” between flame retardants made of different chemicals); *Sungard*, 172 F. Supp. 2d at 189.

1. Plaintiffs’ “Outsourced Hydrophilic Coatings” Market Does Not Survive Scrutiny Under The *Brown Shoe* “Practical Indicia”

257. *Brown Shoe* provides a series of “practical indicia” that courts may consider in determining whether Plaintiffs have properly defined a relevant product market. The indicia include “industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” *Brown Shoe*, 370 U.S. at 325.

258. These “practical indicia” are meant to ensure the Plaintiffs’ market share analysis reflects the commercial realities of the industry at issue. *See Ky. Speedway v. NASCAR, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009) (“practical indicia come into play only after the ‘outer boundaries of a product market are determined’ by evaluating ‘the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it’”) (quoting *Brown Shoe*, 370 U.S. at 325); *U.S. Sugar*, 73 F.4th at 206 (finding the court did not err in “considering facts on the ground” rather than relying on a discredited HMT analysis).

259. The evidence confirms that Plaintiffs’ market is not likely to withstand scrutiny under the *Brown Shoe* practical indicia. Section IV. Proposed markets that do not accord with the practical indicia—presumably because the plaintiff wishes to increase the defendant’s market share—are regularly rejected. *See, e.g., Sungard*, 172 F. Supp. 2d at 182 (finding “extremely heterogeneous group of customers” compelled conclusion that government did not meet its burden to define a relevant market); *In re Harley-Davidson Aftermarket Parts Mktg., Sales Pracs. & Antitrust Litig.*,

__ F.4th __, 2025 WL 2374859, at *7-8 (7th Cir. Aug. 15, 2025) (rejecting narrow alleged market); *Lundbeck*, 650 F.3d at 1242 (rejecting FTC’s overbroad product market that included both drugs at issue); *Kaiser Aluminum*, 652 F.2d at 1332 (affirming FTC’s relevant market was overbroad).

a. UV Versus Thermal

260. With respect to UV versus thermal-cured hydrophilic coatings, the evidence undoubtedly shows that the industry recognizes that they are not substitutable for a significant number of applications, regardless of any hypothetical increase in price. Sections II.A., II.D-E. This is so because of the peculiar uses of each: as discussed, and by way of example, UV cannot be used on inner diameters of catheters, while thermal cannot be used on substrates that may melt. *Id.* Testimony also confirmed that UV and thermal require different facilities and have different curing times and batch sizes. Section II.D. Certain customers are unwilling to switch between them, even if both are possible solutions, given their existing unique production facilities or limited capacity for one type of curing equipment. *Id.* Because every device has unique characteristics and needs, coatings must be tested to determine whether a particular coating will work at all; competitive considerations arise only if UV and thermal coatings both pass feasibility testing. Sections II.D-E. Lastly, it is undisputed that until recently, many hydrophilic coatings suppliers specialized in either UV or thermal, but not both. Section II.E. In fact, Biocoat introduced a UV-cured offering and Harland introduced a thermal coating precisely because thermal and UV-cured coatings are not readily interchangeable. ¶¶ 53-54.

b. Hydrophilic Versus Hydrophobic

261. Testimony also indicated that industry players recognize that hydrophobic material can be used for some of the same applications as hydrophilic coatings because, although the method for providing lubricity differs, they serve the same purpose—providing a slippery surface. For example, guidewires are often coated with PTFE, but also may use a hydrophilic coating. Sections II.A, II.D,

II.E. And hydrophobic material can substitute for thermal-cured hydrophilic coatings on the inner diameter of a medical device. *Id.* The same customers purchase both types of materials, and large vendors such as Integer are experienced in working with both types. Section III.C.1.

c. Outsourced Versus In-House

262. Plaintiffs’ only argument for excluding in-house coatings from the relevant product market is that some customers do not have this option. Tr. 1952:10-15 (Pls. Closing). But “courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this ‘captive output’ (i.e. the self-production of all or part of the relevant product) should be included in the same market.” *Sungard*, 172 F. Supp. 2d at 186 (quoting *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 48 (D.D.C. 1998)) (brackets omitted); *Spectrofuze Corp. v. Beckman Instruments, Inc.*, 575 F.2d 256, 277-78 (5th Cir. 1978) (product market of “servicing Beckman scientific instruments” included large institutions’ “in-house service personnel”); *United States v. Int’l Tel. & Tel. Corp.*, 1971 WL 541, at *10 (N.D. Ill. July 2, 1971) (“in defining the market no legitimate distinction can be drawn between food service provided by outside contractors and food service supplied by the [facility] itself”). Notably, Plaintiffs’ rationale for excluding outsourced would sever UV and thermal-cured into separate markets, if applied consistently.

2. Plaintiffs Are Unable To Define A Relevant Market Using Dr. Fix’s HMT

263. Dr. Fix’s HMT cannot support Plaintiffs’ “outsourced hydrophilic coatings” market. “The HMT asks if a single firm that controlled the entire market (as defined by the FTC) could profitably impose a price increase—as opposed to losing so much business in response that the increase would be unprofitable.” *Tempur Sealy*, 768 F. Supp. 3d at 826.

264. The HMT must start with “the most narrowly-defined product or group of products” and only expand to add more products if the price increase would not be profitable. *Arch Coal*, 329 F. Supp. 2d at 120. Once the narrowest product market passes the HMT, *any* proposed market that includes

that narrowest market will also pass the HMT. For this reason, the HMT cannot reveal a market to be too broad, only too narrow. *RAG-Stiftung*, 436 F. Supp. 3d at 299 n.11; *see* Tr. 1253:7-11 (Fix).

265. Dr. Fix’s HMT shows that narrower markets, such as UV coatings, also pass, meaning Plaintiffs’ market definition violates the narrowest market principle. Section IV.D. Because the narrower market passes, Plaintiffs’ proposed market will necessarily pass Dr. Fix’s HMT too. *Id.*

266. Dr. Fix’s HMT also is unreliable because he *assumes* the diversion from products inside the proposed market to products outside that market is very low, without analyzing actual diversion. Section IV.D. This assumption is at odds with evidence that customers choose alternatives to outsourced hydrophilic coatings. Sections II.A, II.C-D. As the Seventh Circuit has observed, “[t]his Court requires that a plaintiff prove that products are good substitutes using economic evidence; a conclusory assumption of competition where products or services appear to be similar is insufficient.” *Reifert v. S. Cent. Wis. MLS Corp.*, 450 F.3d 312, 318 (7th Cir. 2006). Other courts have likewise held in rejecting the government’s proposed markets in merger challenges. *See, e.g., Tempur Sealy*, 768 F. Supp. 3d at 828 (rejecting HMT where “the model’s parameters and inputs appear designed to produce the outcome sought, without accord to market realities”); *FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 70 (D.D.C. 2009) (“The main problem with [expert]’s models is that the data and predictions cannot reasonably be confirmed by the evidence on this record.”); *see also U.S. Sugar Corp.*, 73 F.4th at 205-06 (district court properly “consider[ed] facts on the ground rather than rely[] upon HMT analysis”).

267. Because Plaintiffs cannot show a relevant market—through the *Brown Shoe* practical indicia or HMT—they cannot establish a *prima facie* case. *See RAG-Stiftung*, 436 F. Supp. 3d at 310; *United States v. Sabre Corp.*, 452 F. Supp. 3d 97, 136 (D. Del. 2020) (holding that DOJ failed to establish a *prima facie* case where it failed to identify a relevant market), *vacated on other grounds*,

2020 WL 4915824 (3d Cir. July 20, 2020); *U.S. Sugar*, 73 F.4th at 207 (DOJ did not establish its *prima facie* case because it failed to “articulate a relevant product market”).

B. Plaintiffs Failed To Reliably Demonstrate Undue Concentration In Any Relevant Market

268. As the second part of their *prima facie* case, Plaintiffs must show that the merger will lead to undue concentration in their alleged market. To do so, Plaintiffs’ “market concentration statistics ... must be relevant to the focus of competition” and “an accurate measure of *future ability* to compete in a relevant market.” *Kaiser Aluminum*, 652 F.2d at 1341 (emphasis added); *see also Ball Mem’l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986) (“Market share reflects current sales, but today’s sales do not always indicate power over sales and price tomorrow.”); *United States v. Int’l Harvester Co.*, 564 F.2d 769, 773 (7th Cir. 1977) (similar); *United States v. Waste Mgmt., Inc.*, 743 F.2d 976, 982 (2d Cir. 1984) (“a substantial existing market share is insufficient to void a merger where that share is misleading as to actual future competitive effect”). Market concentration statistics derived from market shares which do not reflect current and future competitive realities cannot carry Plaintiffs’ burden. *See RAG-Stiftung*, 436 F. Supp. 3d at 319.

269. Plaintiffs present market shares for their outsourced hydrophilic coatings market based on revenues. Sections V.A-B. Defendants’ current revenues do not measure current or future competition because, as discussed, they are derived almost entirely from long-term contracts won years and, in some cases, decades ago. Sections II.H, V.

270. In *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 501 (1974), the Supreme Court held that market shares based on sales and production were not an accurate indicator of market concentration because the “bulk” of the product was “delivered under long-term requirements contracts,” meaning that “such sales [did] not represent the exercise of competitive power but rather the obligation to fulfill previously negotiated contracts at a previously fixed price.” Because “[t]he

focus of competition in a given time frame is ... on the procurement of *new* long-term supply contracts,” the fact that *past* long-term supply contracts indicated concentration was not indicative of current and future competition. *Id.* (emphasis added).

271. Plaintiffs suggest that *General Dynamics*’s holding is limited to cases involving capacity-constrained resources. Tr. 2017:1-17 (Pls. Closing) (noting that “Defendants’ hydrophilic coatings are not a finite natural resource like coal”). That is wrong. Indeed, the Seventh Circuit rejected such a “restrictive” interpretation in *Kaiser Aluminum & Chemical Corp. v. FTC*, 652 F.2d at 1341, where it “interpreted *General Dynamics* to mean that defendants could counter statistical evidence of market concentration by ‘showing’ that concentration ratios ‘gave an innacurate account’ or ‘did not accurately depict’ the probable effects of the acquisition on competition.” *Id.* at 1336. The Seventh Circuit added that other evidence may “cast[] doubt on the persuasive quality of the statistics to predict future anticompetitive consequences.” *Id.* at 1341.

272. Other courts have likewise held. *See, e.g., Waste Mgmt.*, 743 F.2d at 982 (“Moreover, under *General Dynamics*, a substantial existing market share is insufficient to void a merger where that share is misleading as to actual future competitive effect.”); *Ortho Diagnostic Systems v. Abbott Laby’s*, 920 F. Supp. 455, 461-62 (S.D.N.Y. 1996) (applying *General Dynamics* to market shares of medical tests purchased under long-term contracts).

273. The FTC’s 2023 Merger Guidelines also recognize this principle: “Revenues earned from recently acquired customers (or paid to recently acquired buyers, in the case of merging buyers) may provide a useful measure of competitive significance of firms in cases where trading partners sign long-term contracts, face switching costs, or tend to re-evaluate their relationships only occasionally.” DOJ & FTC Merger Guidelines § 4.4.B (2023).

274. Here, consistent with *General Dynamics* and the 2023 Merger Guidelines, Defendants’ revenues are “[e]vidence of past” competitive wins that are inconsistent with recent wins, showing that they do not reflect current competitive dynamics. *Gen. Dynamics*, 415 U.S. at 501. In such circumstances, current revenue “does not, as a matter of logic, necessarily give a proper picture of the company’s future ability to compete.” *Id.* Instead, the “focus of competition” for coating suppliers “is not on the disposition of [product] already produced but on the procurement of new long-term supply contracts.” *General Dynamics*, 415 U.S. at 501.

275. Medical devices locked in to Surmodics or Biocoat years ago that ultimately became blockbuster sellers—generating significant revenue for Surmodics or Biocoat today—do not indicate the merging parties’ ability to currently compete for new devices against Harland, DSM, ISurTec, Hydromer, and other competitors. *See id.* at 501-02; *see also Waste Mgmt.*, 743 F.2d at 982 (“artificially restricted” market definition “may yield market share statistics that are not an accurate proxy for market power” and “future competitive effect” of a merger).

276. Having analyzed Defendants’ revenues based on contract dates, Dr. Wong found that (i) the vast majority of revenues for Biocoat were driven by customers first won at least five years ago and (ii) the vast majority of revenues for Surmodics were driven by projects more than five years old. Sections II.H, V.A (90% of Biocoat’s revenues are legacy).

277. Dr. Wong also analyzed market shares using FDA data, reflecting actual coating selections on devices that were successfully developed beyond feasibility testing. Sections V.A, V.E. These shares, using Plaintiffs’ proposed market definition and even without the Divestiture, show an unconcentrated market, with Biocoat’s and Surmodics’s combined share falling below the 30% required to benefit from a presumption that the merger will result in a substantial lessening of

competition based on market concentration. *See United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1108 (N.D. Cal. 2004) (discussing *United States v. Phila. Nat. Bank*, 374 U.S. 321 (1963)).

278. Plaintiffs’ failure to define a relevant market and establish concentration in that market means they cannot establish their *prima facie* case under Step 1 of *Baker-Hughes*, which ends the analysis. *See RAG-Stiftung*, 436 F. Supp. 3d at 310 (“[A] party’s failure to make out a *prima facie* case is generally considered a ‘fundamental defect’ that dooms its case”); *Tenet Health*, 186 F.3d at 1051 (finding it “essential that the FTC identify a credible relevant market before a preliminary injunction may properly issue”); *Arch Coal*, 329 F. Supp. 2d at 116 (“[A] failure of proof in any respect will mean the transaction should not be enjoined.”).

C. Plaintiffs Cannot Save Their *Prima Facie* Case By Arguing That The Merger Eliminates Head-to-Head Competition

279. Having failed to establish a *prima facie* case—by showing that the transaction is likely to lead to undue concentration in a relevant antitrust market—Plaintiffs argue in the alternative that they can establish their *prima facie* case by showing that “the Proposed Acquisition would eliminate substantial head-to-head competition between two close competitors.” Dkt. 173 at 32 (internal quotations omitted); Tr. 1953:15-24 (Pls. Closing) (arguing that elimination of “close, head-to-head competition between Biocoat and Surmodics” is an “independent bas[i]s” for finding the transaction “is substantially likely to lessen competition”). That is not the law.

280. Plaintiffs cannot evade their burden by failing to put forward a relevant market, which is a “necessary predicate” to a Section 7 claim. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (“substantiality can be determined only in terms of the market affected”); *see also Tenet Health*, 186 F.3d at 1051 (“Without a well-defined relevant market, a merger’s effect on competition cannot be evaluated. It is thus essential that the FTC identify a credible relevant market before a preliminary injunction may properly issue.”); *FTC v. Thomas Jefferson Univ.*, 505 F. Supp.

3d 522, 539 (E.D. Pa. 2020) (“To determine whether a proposed merger is reasonably likely to violate the Clayton Act, it is first necessary to determine the relevant geographic and product markets.”); *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1036 (D.C. Cir. 2008) (rejecting as “[i]nexplicabl[e]” the FTC’s argument that “a market definition is not necessary in a § 7 case”).

That is because permitting Plaintiffs’ amorphous definition of “head-to-head competition” to include any instance that the parties sought the same opportunity is manifestly inconsistent with *Brown Shoe*.

281. Nor can Plaintiffs evade their *prima facie* burden by failing to put forward an analysis showing undue concentration in their proposed market. As one court recently observed in response to a similar FTC argument, “The Court is unaware of a single case in which a court has enjoined a merger, even at this preliminary stage, where the Government failed to show undue concentration in a relevant market as its *prima facie* case requires.” *RAG-Stiftung*, 436 F. Supp. 3d at 310. Indeed, Plaintiffs’ few anecdotal examples are insufficient to show the loss of competition would be *substantial*. To require anything less would impermissibly shift the burden of proof to Defendants.

282. Plaintiffs do not cite a single case supporting their assertion that elimination of direct competition provides an independent basis to meet their *prima facie* case. Instead, every case they cited for this proposition in their pre-hearing brief found a relevant market *and* undue concentration in that market as the basis for finding that the plaintiffs established their *prima facie* case. *See ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 568, 572 (6th Cir. 2014) (affirming definition of relevant markets and finding “any argument about substitutes must begin with a definition of the relevant market”); *IQVIA*, 710 F. Supp. 3d at 382 (finding the FTC had established its *prima facie* case by defining a relevant market and showing increased concentration through market shares and an HHI calculation); *FTC v. The Kroger Co.*, 2024 WL 5053016, at *17 (D. Or. Dec. 10, 2024) (noting that “plaintiffs have already met their *prima facie* burden based on the post-merger changes

in market concentration”); *FTC v. Tapestry*, 755 F. Supp. 3d 386, 485-86 (S.D.N.Y. 2024) (evaluating “additional evidence of anticompetitive effects,” including elimination of head-to-head competition, at “Step 3”); *Sysco*, 113 F. Supp. at 61 (evaluating additional evidence of competitive harm after FTC established its *prima facie* case through market concentration statistics).

283. This Court should reject Plaintiffs’ invitation to be the first court to dispense of Plaintiffs’ obligation to identify a relevant market and show undue concentration as the foundation for their *prima facie* Section 7 case.

XI. STEP 2: DEFENDANTS ARE LIKELY TO REBUT PLAINTIFFS’ PRIMA FACIE CASE

284. Even if Plaintiffs satisfied their burden to show a *prima facie* case, Defendants can rebut the presumption that the transaction is anticompetitive by demonstrating that “statistics on market share, market concentration, and market concentration trends portray inaccurately the merger’s probable effects on competition.” *Baker Hughes*, 908 F.2d at 991 (quotation omitted); *see also id.* at 992 (“market power,” not market share, “is the ultimate consideration”). “Evidence of market concentration simply provides a convenient starting point for a broader inquiry into future competitiveness.” *Id.* at 984. The quantum of evidence Defendants must produce to shift the burden back to Plaintiffs in Step 3 is low where, as here, Plaintiffs’ *prima facie* case is weak. *Arch Coal*, 329 F. Supp. 2d at 129 (“Certainly less of a showing is required ... to rebut a less-than-compelling *prima facie* case.”).

285. Contrary to Plaintiffs’ repeated assertion, Defendants never have the burden to prove the acquisition *does not* violate Section 7; rather, they must only rebut the presumption of illegality by presenting evidence that the government’s market share statistics “produce an inaccurate account of the merger’s probable effect on competition.” *Arch Coal*, 329 F. Supp. 2d at 116.

A. Plaintiffs' Revenue-Based Market Shares Inaccurately Reflect The Modified Transaction's Probable Effects On Competition

286. Plaintiffs' market share statistics based on legacy revenue from long-term contracts do not reflect current market realities. For the same reasons that Plaintiffs' revenue-based market shares do not establish undue concentration, the shares also do not accurately reflect the transaction's probable effect on current and future competition. Section X.B; *Arch Coal*, 329 F. Supp. 2d at 129.

B. The Divestiture Eliminates Any Possibility Of Anticompetitive Effects

287. Plaintiffs' statistics also inaccurately predict the merger's probable effects on competition because they ignore the Divestiture. If the Court addresses the Divestiture as part of Defendants' rebuttal burden rather than Plaintiffs' *prima facie* case, the outcome is no different because the Divestiture package provides even further assurance that, going forward, past shares will not be indicative of future harm. *See Arch Coal*, 329 F. Supp. 2d at 147-48 (divestiture buyer's "credible plans to expand production" lessened risk of anticompetitive effects post-merger).

288. Courts evaluating a divestiture's effect on competition consider several factors, including: (1) the likelihood of the divestiture; (2) the experience of the divestiture buyer; (3) the scope of the divestiture; (4) the independence of the buyer from the merging seller; and (5) the purchase price. *Tempur Sealy*, 768 F. Supp. 3d at 858; *RAG-Stiftung*, 436 F. Supp. 3d at 304. The Divestiture meets each of these considerations.

289. *First*, the Divestiture is certain, contingent only on the merger closing. Section III.B.

290. *Second*, Integer is a robust buyer, with significant experience in the industry, uniquely positioned to compete immediately on Day One. Section III.C. "[T]he evidence at trial established ... that [divestiture buyer's] incentives are geared toward preserving, and even improving, [divested business's] competitive edge." *UnitedHealth*, 630 F. Supp. 3d at 136. Plaintiffs claim that Integer lacks experience manufacturing hydrophilic coatings specifically, but the standard is whether Integer

has *relevant* experience. *Id.* at 135 (finding buyer “has the experience necessary to compete effectively in the claims editing market” in part because “[t]he evidence also demonstrated that [the buyer] has significant experience in the healthcare industry”). Integer not only has ample experience applying hydrophilic coatings, but it recently acquired two companies that manufacture and apply non-hydrophilic coatings. Section III.C.4.

291. *Third*, Biocoat is divesting all components needed to make Integer a successful competitor in both UV and thermal, including all currently marketed products and the entirety of Biocoat’s UV-cured business. Section III.C.5. Divestiture of a “standalone business” is not required when “the evidence shows that the [divested facility] comes along with everything else that’s needed to run a standalone business.” *RAG-Stiftung*, 436 F. Supp. 3d at 305 (cleaned up); *see* FTC, Bureau of Competition, Statement on Negotiating Merger Remedies (Jan. 2012) at 6-8, <https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf>.

292. Plaintiffs provide only speculation about what else Integer might need to compete. Neither Plaintiffs nor Dr. Fix have run a coatings business and cannot selectively ignore facts presented by Integer itself. *See Arch Coal*, 329 F. Supp. 2d at 116-17. The legacy thermal coatings Biocoat is retaining to continue to serve legacy customers will not affect Integer’s ability to compete for new customers. Section III.C. The license-back of Biocoat’s currently marketed thermal coatings also will not undermine Integer’s ability to compete because it has other “value propositions” that Biocoat does not. Section III.C.3. Finally, Plaintiffs assert that brand loyalty is key and will impact Integer’s ability to compete. Tr. 1971:7-23, 2017:25-2018:5 (Pls. Closing). Yet, Plaintiffs ignore that both the HYDAK brand and the Biocoat name will transfer to Integer, addressing this professed concern.

293. While Plaintiffs prefer divestiture of a “standalone business,” their preference does not mean the Divestiture here is insufficient. Courts regularly approve partial divestitures. *See, e.g., Tempur*

Sealy, 768 F. Supp. 3d at 858, 862 (denying preliminary injunction where Tempur Sealy committed to divest certain stores, distribution centers, and commercial office space); *RAG-Stiftung*, 436 F. Supp. 3d at 305, 322 (denying preliminary injunction over FTC’s arguments that the divestiture buyer “is buying [only] a ‘standalone plant’ and not a ‘standalone business’”); *UnitedHealth*, 630 F. Supp. 3d at 138-39 (finding divestiture of single product resolved horizontal theory of harm, and rejecting government’s argument that product was marketed and sold as part of software suite and would not be successful alone). Likewise, the FTC and DOJ routinely accept partial divestitures as remedies to resolve Section 7 concerns. Tr. 50:14-17 (Defendants’ opening statement slide 31).

294. *Fourth*, Integer will not be reliant on Biocoat going forward. While there is a Transition Services Agreement (“TSA”) with a one-year term, these agreements are typical in such transactions, as assets, customer contracts, and manufacturing facilities cannot be instantly transferred and ramped up. *See United States v. Bayer AG*, 2019 WL 1431903 (D.D.C. Feb. 8, 2019) (approving settlement including detailed transition services agreement to facilitate divestiture); *see also* Section III.C.5. In fact, the FTC remedies guide contemplates the use of TSAs for partial divestitures. *See* FTC, Bureau of Competition, Statement on Negotiating Merger Remedies (Jan. 2012) at 15.

295. *Fifth*, the Divestiture’s purchase price reflects an arms’-length negotiation. Although Plaintiffs object that the purchase price is lower than what BC Holdings paid to acquire Biocoat in 2022, and that the Divestiture does not include revenue from all legacy contracts, that is not the relevant question.⁴ Rather, the question is whether Integer is positioned to compete with other hydrophilic coatings providers such that the transaction is unlikely to substantially reduce

⁴ Plaintiffs’ criticism that the purchase price is too low is the same as their criticism that the Divestiture does not include Biocoat’s legacy revenues. The purchase price is lower than when the Strategic Growth Fund invested in Biocoat in 2022 because it purchased what was in effect a “durable annuity investment[]” due to legacy revenues. Tr. 1331:10-25 (Hance); ¶ 137.

competition in a relevant market; the only evidence before the Court shows that Integer intends to compete vigorously and has the resources to be successful. That is sufficient. *See Tempur Sealy*, 768 F. Supp. 3d at 858 (“[A]lthough the purchase price is low, there is no doubt that [divestiture buyer] intends to use the divested [assets].”); *RAG-Stiftung*, 436 F. Supp.3d at 307 (“[T]o state the obvious, a potential buyer of an asset sold to facilitate a merger under scrutiny ... has enormous leverage over the seller because it knows the seller must divest the asset quickly ...”).

296. Plaintiffs’ cited cases provide no basis to reject the Divestiture, and instead involved fact-specific findings that the scope of the divested assets, the buyer’s inexperience, and the buyer’s ongoing dependence on the merged entity raised serious questions about the buyer’s ability to compete effectively and independently. *See, e.g., Kroger*, 2024 WL 5053016, at *26-30 (“The deficiencies in the divestiture scope and structure create a risk that some or all of the divested stores will lose sales or close, as has happened in past C&S acquisitions.”); *United States v. Aetna*, 240 F. Supp. 3d 1, 64-74 (D.D.C. 2017) (finding “reasons to doubt” the divestiture buyer would be successful given lack of experience, small size relative to the divested assets, and internal documents expressing doubt about necessary capabilities); *Sysco*, 113 F. Supp. 3d at 73-78 (noting limited geographic scope of divested assets, significantly smaller size of divestiture buyer, and possible dependence on merged firm for up to 10 years).

297. Nor can Plaintiffs defeat the merger by arguing that the Divestiture must fully restore the competition lost as a result of the deal. Tr. 12:8-19 (Pls. Opening) (“It is defendants’ burden to show that their proposed remedy similarly eliminates the effects of the illegal acquisition. ... [D]efendants [must] produce evidence showing that the divestiture will restore the competition and the competitive intensity lost due to the merger. ... The goal of a divestiture is to replace the competition lost from the merger by creating a new, independent competitor, a new Biocoat.”). Again, that is

not the law. *See Illumina, Inc. v. FTC*, 88 F.4th 1036, 1059 (5th Cir. 2023) (“Illumina was only required to show that the [remedy] sufficiently *mitigated* the merger’s effect such that it was no longer likely to *substantially* lessen competition.”); *UnitedHealth*, 630 F. Supp. at 133 (rejecting argument that defendant “must prove that the divestiture will maintain the *same* level of competition that existed in the pre-merger market” as “contradict[ing] the text of Section 7 and the *Baker Hughes* framework”).⁵ And with good reason—under Plaintiffs’ standard, every transaction eliminating a competitor, big or small, would be illegal because, by definition, it would not restore the market to the same level of competition that existed pre-transaction. Section 7 provides the FTC only with authority to block transactions that are likely to *substantially* lessen competition in a relevant market. 15 U.S.C. § 18. Defendants’ commitment to the Divestiture means this transaction will not do so.

XII. STEP 3: PLAINTIFFS CANNOT CARRY THEIR ULTIMATE BURDEN OF PERSUASION TO PROVE THE TRANSACTION IS LIKELY TO PRODUCE ANTICOMPETITIVE EFFECTS IN ANY RELEVANT MARKET

298. If the analysis proceeds to Step 3, Plaintiffs must prove that they are likely to prevail on the merits of their claim that the Modified Transaction is likely to have substantial anticompetitive effects in a relevant market. They are unable to do so.

299. Because “some lessening of competition” is not sufficient to block a merger, *Int’l Shoe*, 280 U.S. at 298 (Section 7 “deals only with such acquisitions as probably will result in lessening competition to a substantial degree”), Plaintiffs must provide a forward-looking analysis of how the transaction likely will harm consumers. *See Baker Hughes*, 908 F.2d at 988, 991 (merger analysis “focus[es] on the future” and requires court to “[p]redict[] future competitive conditions”).

300. Plaintiffs’ only theory of harm is that merger will cause the loss of head-to-head competition

⁵ Plaintiffs’ cited case agrees. *See Kroger*, 2024 WL 5053016, at *24 (“[D]ivestiture is successful rebuttal evidence if it ‘sufficiently mitigate[s] the merger’s effect such that it [is] no longer likely to substantially lessen competition.’”) (quoting *Illumina*, 88 F.4th at 1059).

between Biocoat and Surmodics. The loss of head-to-head competition may create these kinds of “unilateral anticompetitive effects” if the merged firm “will have the incentive to raise price or reduce quality” without regard for the “competitive responses from other firms.” *Aetna Inc.*, 240 F. Supp. 3d at 43. Plaintiffs fail to provide the type of evidence usually cited in Section 7 cases as proof of likely anticompetitive effects, including: (i) ordinary course documents indicating that the acquired company was a competitive restraint on the acquirer; (ii) documents showing the acquirer intended to raise prices or otherwise harm customers post-merger; or (iii) reliable economic analyses.

301. *First*, as a threshold matter, Plaintiffs did not present the type of competitive pressure or head-to-head competition that is the focus of Section 7 law—competition that affects price, quality, or innovation, the elimination of which will harm consumers. *See New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 238-39 (S.D.N.Y. 2020) (finding loss of “direct competition” between firms insufficient to show likelihood the merger would substantially lessen competition because merged firm would still need “to differentiate” from other competitors and divestiture buyer). Instead, Plaintiffs attempt to establish meaningful head-to-head competition between Biocoat and Surmodics based on documents showing they are both industry players and are occasionally tested by the same customers. Critically, Plaintiffs failed to show any instance where either Defendant leveraged this head-to-head competition to receive a better price or other more favorable terms. Sections II.D, VI.D. Customers instead testified that they do not play coating suppliers off one another to get a better price and are not concerned about the transaction. Sections II.D, VI.D-E.

302. This contrasts with the evidence of ordinary course head-to-head price competition in cases where courts have enjoined transactions. *See, e.g., United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 217 (D.D.C. 2017) (customers solicited bids from the four large health insurers (including defendants) and “play[ed] the top bidders against each other”); *FTC v. Staples, Inc.*, 190 F. Supp. 3d

100, 120 (D.D.C. 2016) (customers solicited RFPs and “pit Defendants against each other” in the bidding process); *Whole Foods*, 548 F.3d at 1040 (evidence that prices declined when a Whole Foods opened near a Wild Oats); *Kroger*, 2024 WL 5053016, at *17 (testimony about “data analytics and pricing strategy shows that defendants monitor and respond to each other’s pricing,” including keeping prices within a certain range or lower than a competitor’s prices); *IQVIA*, 710 F. Supp. 3d at 383, 386 (evidence of price reductions because of the other merging party’s competing bids and quantitative analysis of “actual customer choices and pricing incentives” that showed price reductions because of the other merging party); *H & R Block*, 833 F. Supp. 2d at 82 (“HRB has lowered its DDIY prices to better compete with free online products ... and has directly considered TaxACT’s prices in setting its own prices”); *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 63 (D.D.C. 2018) (customer testimony supports “that competition between them plays a key role in providing consumer benefits”); *Sysco*, 113 F. Supp. 3d at 65 (“documents indicate that Sysco and USF compete aggressively against one another on price; non-price incentives, such as signing bonuses; service; and other value-added offerings”).

303. Even putting aside Integer’s entry into the market with both UV and thermal options, customers will have many choices after the merger. That certain customers like Medtronic may prefer to use both Surmodics and Biocoat does not show that removal of the narrow head-to-head competition between the two is likely to substantially lessen competition. *See Oracle*, 331 F. Supp. 2d at 1169 (finding it undisputed that merging parties “compete frequently” but presence of third competitor meant government failed to show likelihood of anticompetitive effects).

304. *Second*, “unlike many cases in which the FTC alleges that a proposed merger would be anticompetitive, the record contains no evidence that [Defendant] intends to raise prices post-merger.” *RAG-Stiftung*, 436 F. Supp.3d at 320. This lack of evidence contrasts starkly with cases

where the FTC prevailed under Section 13(b). *See, e.g., H & R Block*, 833 F. Supp. 2d at 82; *Whole Foods*, 548 F.3d at 1049; *IQVIA*, 710 F. Supp. 3d at 345, 384; *Wilhelmsen*, 341 F. Supp. 3d at 63 (internal document noted that merger would “increase our ability to charge far better prices”).

305. *Third*, Dr. Fix presented a merger simulation purporting to predict price increases after the merger. It does not help Plaintiffs meet their burden. At a threshold level, the merger simulation ignores the Divestiture and so is irrelevant to the dispositive question here: whether the Modified Transaction is likely to substantially lessen competition in a relevant market. Section VI.F. Any purported effects are in a world that does not and will not exist.

306. Additionally, Dr. Fix’s model relies on his market shares, which as discussed above do not reflect competitive dynamics post-merger. The design is further flawed because it requires customers to view Biocoat and Surmodics as their top two choices—an assumption unsupported by the evidence. Sections II.B-E, VI.A, VI.F. Even accepting Dr. Fix’s model, he admits that he has not tried to calculate the impact of the transaction on any individual customer. *See* ¶ 223.

307. In sum, Plaintiffs are unlikely to carry their ultimate burden of persuasion that this transaction is likely to substantially harm competition in any relevant market.

XIII. THE EQUITIES WEIGH AGAINST AN INJUNCTION

308. Finally, in deciding whether to grant a preliminary injunction under Section 13(b), a court balances the equities. *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1083 (D.C. Cir. 1981). The kinds of equities that may be considered “[are] not qualified” by statute. *Id.* Plaintiffs must “prove that the harm to the parties and to the public that would flow from a preliminary injunction is outweighed by the harm to competition, if any, that would occur in the period between denial of a preliminary injunction and the final adjudication of the merits of the Section 7 claim.” *Great Lakes Chem.*, 528 F. Supp. at 86. Plaintiffs offer no proof of (1) harm to competition in the interim between denial of the injunction and final adjudication, or (2) public harm in the absence of a preliminary injunction.

309. The only public interest invoked by Plaintiffs is preventing the sharing of proprietary information between Defendants. This supposed harm is wholly conclusory and unsupported. And any general public interest in maintaining competitive markets is not served by an injunction given the weakness of Plaintiffs' case. *See Thomas Jefferson Univ.*, 505 F. Supp. 3d at 558. There is no reason to believe that the record in the FTC's administrative proceeding will be materially different than the record developed here. If the Court finds Plaintiffs' case weak, their evidence is unlikely to improve, and an injunction would not serve the public interest. *See Great Lakes Chem.*, 528 F. Supp. at 87 ("[T]he purpose of Section 13(b) is to preserve the ability to 'order effective, ultimate relief,' not to bar all mergers that the FTC staff preliminarily views as suspicious.").

310. Additionally, because the Divestiture "will probably increase competition, no public interest is served by enjoining the proposed transaction." *White Consol. Indus., Inc. v. Whirlpool Corp.*, 781 F.2d 1224, 1228 (6th Cir. 1986).

311. In contrast, if a preliminary injunction is granted, Defendants and Integer would be harmed, as the Modified Transaction would not close. Defendants and Integer intend to invest and innovate to the benefit of medical device manufacturers, doctors, and patients. Sections III.A, III.C. Additional interests are implicated: "Corporations have responsibilities to their shareholders, employees, and customers. Major structural shifts cannot remain in limbo for prolonged or indefinite periods of time." *Tempur Sealy*, 768 F. Supp. 3d at 861.

312. In the final analysis, it is important to ask "who would be helped and who would be hurt by allowing—and who by forbidding—a challenged acquisition to go through before what are often protracted administrative proceedings are completed." *Elders Grain*, 868 F.2d at 904. Plaintiffs have presented no answer to who would be hurt by allowing the acquisition, and the equities accordingly weigh in favor of Defendants.

Date: September 16, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.9, I hereby certify that on this 23rd day of September 2025, the foregoing was electronically filed using the Court's CM/ECF system and was also served via electronic mail to the following:

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